No. 15357

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

HANS S. HOLLANDER and CLEMENCE BLUM HOLLANDER,
Petitioners,

vs.

COMMISSIONER OF INTERNAL REVENUE,
Respondent.

PETITIONERS' REPLY BRIEF.

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Summary of Reply Brief.

This is a reply brief. We shall not attempt to repeat the arguments already set forth in our main brief. We deal only with the arguments advanced on behalf of the respondent, and with the specific matters in its brief which seem in most urgent need of correction.

The respondent in its brief has attempted to establish the non-deductibility of alimony payments made by Hans S. Hollander to his ex-wife Idy Hollander under the 1948 modifying agreement on what appears to be the followings grounds: one, that the original agreement of 1946 was a "final" and unalterable settlement imposing a support obligation which could not be modified to provide for the revised support payments in question; and two, that the support obligation incurred under the 1948 modifying agreement was a new non-support obligation and a mere gratuity.

No case authority is presented in support of this position, just as none was cited in the Tax Court's opinion below. Moreover, respondent's position is mistaken because the reasons on which it is based are erroneous in law and fact. As a matter of state law, the support obligation imposed by the original agreement and decree of 1946 was at all times subject to valid modification, in the manner in which such modification was actually executed, despite the language of "finality" in the original agreement and decree. Inasmuch as the support obligation under the 1946 agreement and decree was validly modified, the support obligation under the 1948 agreement and decree was obviously not a new obligation but a continuance of the original obligation. In addition, as a matter of fact, the 1948 modifying agreement was bargained for and supported by traditional legal consideration in the form of mutual promises. (See Op. Br. 22-25.) It is fundamental law that where there is legal consideration for a promise, there cannot also be a gift or a mere gratuity.

Respondent in its brief has attempted to distinguish the instant case from *Newton v. Pedrick* and the other cases cited by petitioners (see Op. Br. 11) by limiting to the facts of the prior cases the rule of law developed therein. We submit, however, that the prior cases have developed a general principle of law consistent with legislative policy, namely: that were a legal obligation to support survives the dissolution of the marital relationship, subsequent adjustment of that obligation by later agreement or court order is incident to such divorce. This rule should be determinative of the instant case. As will be pointed out in this brief, respondent's attempt to limit this rule by emphasizing immaterial factual distinctions involves fallacious legal analysis inconsistent with legis-

I.

The Support Obligation Imposed By the Original 1946 Agreement and Decree Was Subject to a Valid Modification, in the Manner in Which Such Modification Was Actually Executed, Even Though Such Agreement and Decree Purported to Be a "Final" Settlement.

The respondent in its brief (Resp. Br. 11-13) and the Tax Court in its opinion [R. 59-62] assert that the original 1946 agreement and decree, at a time when they were in full force and effect, could not be validly modified to provide for reduced payments for a fixed period of years whether or not Idy remarried. The authority given for such assertion by both respondent and the Tax Court is the language of the 1946 agreement and decree which, concededly, declare themselves to be "final" settlements. These assertions by the respondent and the Tax Court, we submit, are based upon a total disregard of State law which recognizes as valid and judicially enforceable the modifications in question and upon an erroneous interpretation and construction of the language of "finality" contained in such original 1946 property settlement agreement and decree.

On June 30, 1948, the Superior Court of the State of California entered its decree establishing the 1946 Nevada decree as a foreign judgment, incorporating the 1948 modifying agreement, and ordering Hans S. Hollander to make the support payments in question.[1] [R. 17, 42-43.] It is submitted that the decree entered by the Superior Court of the State of California conclusively

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[1]Respondent totally without authority and documentation, goes so far in its Brief (Resp. Br. 12, fn. 3) as to assert that the Superior Court of the State of California was exceeding its authority by entering such decree.

demonstrates that the original 1946 agreement and decree were subject to a valid modification by mutual agreement despite their language of purported "finality." (See *Freuler v. Helvering,* 291 U. S. 35 (1934.) The law of the State of California allows court enforcement of revisions of purportedly "final" agreements where the parties have mutually agreed to the revision. (*Miller v. Superior Court,* 9 Cal. 2d 733, 72 P. 2d 868 (1937); Cal. Civ. Code, Sec. 139.) In such cases, the Court has the power to enter a decree incorporating the revised agreement to which both parties have agreed, even though the Court would not have jurisdiction to enter such a decree upon a unilateral petition of one of the parties. So, too, the law of the State of Nevada allows court enforcement of revisions by mutual agreement, even where there is language of "finality" which would prevent revision upon a unilateral petition.[2] (See Nevada Compiled Laws, Supp. 1943-1949, Secs. 9463, 25.)

The State law in this issue is based upon a well-grounded understanding of the purpose of putting "finality" language in a property settlement agreement and decree. Such language of "finality," like almost all legal concepts, is not to be read literally and out of context in the manner of the Tax Court and respondent, but is to be read in the light of the intent of the parties to the agreement and of the purpose to which the inclusion of the language was to serve. Language of "finality" in

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[2]There is no conflict of laws issue present since the law of California and Nevada, the only states interested in the transaction, are exactly the same on this point.

a settlement agreement is used only to prevent harassment of one party by unilateral petition on the part of the other party to a court to upset the mutually agreed-upon arrangement of the parties. The inclusion of such "finality" clauses in agreements are commonplace since the purpose of having such a "finality" provision in an agreement is that its presence gives the parties certainty and predictability in their parting arrangements. One party cannot cause a change unless the other party agrees to it. It is fundamental, however, that parties to a contractual agreement can always modify their contract by another mutual agreement. Moreover, changing circumstances such as the economic position of the ex-husband or the economic needs of the parties, or their children, frequently dictate in the property settlement area that the parties renegotiate the terms of a purportedly "final" settlement. In such situations where there are changed circumstances, because of the inability of either party to revise the parting arrangements upon a unilateral petition to a court, it becomes very important from the standpoint of public policy to allow revision by mutual agreement. Yet the Tax Court and the respondent would not only deny that revision of continuing support obligations are justifiable from the standpoint of public policy, but they would go so far as to deny that such revisions are even legally possible. It is submitted that the Commissioner of Internal Revenue and the Tax Court are wrong as a matter of law and are incorrect as a matter of sound public policy.

II.

The Support Obligation Imposed by the 1948 Modifying Agreement and Decree Was Neither a New Obligation nor a Mere Gratuity.

The respondent in its brief (Resp. Br. 10-13) treats the 1948 modifying agreement as if it gave rise to a new non-support obligation of Hans S. Hollander which was unrelated to the support obligation arising from the original 1946 property settlement and agreement. Inasmuch as the support obligation under the 1946 agreement and decree was validly modified, the support obligation under the 1948 agreement and decree was obviously not a new obligation but a continuance of the original obligation.

Despite the fact that the 1948 support obligation was not a new obligation but a continuance of the original obligation, the respondent asserts that the support obligation imposed by the 1948 modifying agreement and decree was a mere gratuity following Idy's remarriage. (Resp. Br. 9, 16.) Therefore, the respondent must in effect be treating the facts as if Idy Hollander had remarried prior to the execution of the modifying agreement of 1948; if such were the case, then there could be no consideration for the support obligation under the 1948 modifying agreement because Hans S. Hollander, by such modifying agreement would then have been reviving an obligation of which he had been relieved or assuming an obligation which had never before been present. Even though the stipulated facts state precisely that Idy Hollander had not remarried on March 16, 1948 [R. 17], the respondent asserts it is "realistic" to consider Idy Hollander as being remarried on March 16, 1948. (Resp. Br. 16.) There is no evidence in the record which would

support a position by the Tax Court or the Government that Idy had *in reality* remarried on such date. In truth, the facts stipulate that the modifying agreement "enabled" Idy to remarry, which fact raises the inference that Idy would not have been able to remarry if she had been unable to secure such agreement. [R. 17.] As far as Hans S. Hollander was concerned, on March 16, 1948, he was under a fully enforceable legal obligation to support Idy Hollander for the rest of her natural life. The only way in which Hans S. Hollander could be relieved from his fully enforceable support obligation was by securing Idy's consent to relief or by an act (Idy's remarriage) over which Hans had no control and which was entirely within the discretion and whim of two independent parties, Idy and her prospective husband. Even though Hans knew Idy was strongly considering remarriage, it was a fact that on March 16, 1948, Idy Hollander had not only not remarried but might never have remarried for any number of reasons such as an accident to or change of heart by Idy or her prospective husband. Thus, the 1948 agreement was the result of a bargained for exchange of mutual promises which saw both parties suffering legal detriments as promisors and receiving legal benefits as promisees. (See Op. Br. 22-25.) Hans S. Hollander's promise to make payments whether or not Idy remarried was no act of mere generosity, such as it would have been had Idy Hollander remarried prior to March 16, 1948.

Hans S. Hollander did not assume any new non-support obligations because on March 16, 1948, he had been relieved of none of his support obligations under the original 1946 agreement and decree. If Hans S. Hollander can be said to have "voluntarily" assumed

any burdens by reason of the modifying agreement, such statement is meaningful only in the sense that any contractual relationship can be said to be "voluntarily" assumed; there is freedom to contract or not to contract and the execution of a contract is a volitional act. Indeed, every property settlement is a "voluntary" agreement of the parties. The respondent's assertion that a gratuity was involved is contrary to the facts and basic legal principles. The 1948 agreement and decree carried on without interruption the original support obligation imposed by the 1946 agreement and decree.

III.

The Instant Case Falls Within a Clearly Established Rule of Law Which Properly Implements Legislative Intent.

As petitioner stated in its opening brief (Op. Br. 10-12), the rule of law applicable to this case is as follows: Where a legal obligation to support under an existing agreement incident to the divorce survives the dissolution of the marital relationship, subsequent adjustment of that obligation by later agreement or Court order is "incident to such divorce."

Although there are a substantial number of cases which have developed this rule (see Op. Br. 11), respondent would like to limit each one of those cases to its facts, and by so doing, limit the generality of the rule which the courts have developed. (See Resp. Br. 17-22.) As an example of respondent's technique of finding factual differences which are without legal significance, consider the leading case of *Newton v. Pedrick,* 212 F. 2d 357 (2nd Cir., 1954), reversing 115 Fed. Supp. 368 (S.D.N.Y., 1953). The original agreement in that case required the taxpayer to make payments to

his former wife of $24,000 annually for life, or until her remarriage, and $14,000 annually after her remarriage. At a time when the ex-wife had already remarried and thus the ex-husband's original obligation to make the larger payments of $24,000 had terminated, the husband agreed to increase the ex-wife's payments by $11,000 to $25,000 annually in exchange only for the legal custody of the children of the marriage. The Court of Appeals for the Second Circuit allowed the deduction of the entire $25,000, including the $11,000 for which there was no obligation under the original agreement. Similarly, the fact that in the instant case the payments after remarriage were not provided for in the original agreement is immaterial. Moreover, in the instant case, because the ex-wife had not remarried, the modifying agreement *reduced* the husband's support obligation as well as securing for him the legal custody of his child. To state the comparison in another way, in the instant case the obligation to make the reduced payments after the wife's remarriage can be said to be a "new" non-support obligation only in the same sense that in *Newton v. Pedrick* the obligation to pay the extra $11,000 annually after the wife's remarriage could be said to have been a "new" non-support obligation. "New" in point of time, yet related back to the original support obligation because it was a revision of such original support obligation. Although there are admittedly factual differences in the instant case from any previous case, it is submitted that these differences should be considered as without legal significance and the principle of law set forth above should be reaffirmed. The Commissioner of Internal Revenue has been unable to offer any authority or documentation for his position that certain types of support

payments under a bargained for modifying agreement are not deductible. The case of *Cox v. Commissioner,* 176 F. 2d 226 (3rd Cir., 1949), which the Commissioner suggests is similar (see Resp. Br. 22) is distinguishable because it is clearly a case of a gratuity where there was never at any time any enforceable support obligation which survived the dissolution of the marriage.

The merit of a rule that periodic alimony payments are deductible when made pursuant to a modifying agreement which resulted from a bargained for transaction is that such a rule permits taxpayers to adjust their surviving marital obligations in the light of changing circumstances. Sections 22(k) and 23(u) were relief measures added to the Internal Revenue Code to allow an equitable distribution of the tax burdens resulting from the adjustment of marital or family financial obligations in connection with the dissolution of the marriage relationship. Furthermore, as has been pointed out, in prior cases, there is nothing in the statute or its legislative background which suggests that such policy of affording relief was intended to be limited to those arrangements affected at the time of the decree of divorce or separation "without regard to possible future re-arrangements in consequence of later and perhaps *unforeseen* vicissitudes." (Italics supplied.) (See *Newton v. Pedrick,* 212 F. 2d 357 at 361.) The respondent would like to restrict the permissible modifications of an agreement to only those contingencies which the parties foresaw in the original agreement. It is submitted that such a limitation based on

foreseeability would undermine the entire rule permitting modifications; almost by definition, the parties, at the time of the original agreement, did not foresee the contingency which requires the modification, or else they could have taken care of the contingency in the original agreement and there would be no need to modify at all.

It is not without significance that the respondent in its brief did not answer petitioner's argument that the position of the Tax Court, if sustained, would result in freezing a great many taxpayers in their position under alimony arrangements, unless their situation was sufficiently pressing that they were willing to absorb the inequitable tax burdens from which Congress once tried to relieve them. The truth is that the Commissioner of Internal Revenue, by seizing upon incidental and irrelevant factual matters, would like to undercut the broad interpretation developed by the Courts of the statutory phrase "incident to such divorce." (See *Harold Holt v. Commissioner,* 216 F. 2d 757 (2nd Cir., 1955), reversing 23 T. C. 469, cert. den., 350 U. S. 982; compare *Commissioner v. Miller,* 199 F. 2d 957 (9th Cir., 1952), reversing 16 T. C. 1010; non-acq. 1951-2 Cum. Bull. 5.)

Conclusion.

The payments made by petitioner, Hans S. Hollander, to his former wife, Idy, during 1948 and 1949 were deductible under Section 23(u) of the Internal Revenue Code of 1939 because such payments were in discharge of a legal obligation arising out of the marital or family

relationship, which obligation was imposed upon petitioner under a decree of divorce and under a written instrument incident to the divorce. The Commissioner of Internal Revenue's determination of a deficiency for those years should be disapproved, and the Tax Court's decision reversed, and judgment entered for the petitioner.

Respectfully submitted,

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No. 13377

In the United States Court of Appeals for the Ninth Circuit

Claude Pharmacal, Inc., petitioner

v.

Federal Trade Commission, respondent

On Petition for the Review of an Order to Cease and Desist

BRIEF FOR RESPONDENT

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In the United States Court of Appeals for the Ninth Circuit

No. 15373

CARTER PRODUCTS, INC., PETITIONER

v.

FEDERAL TRADE COMMISSION, RESPONDENT

ON PETITION FOR THE REVIEW OF AN ORDER TO CEASE AND DESIST

BRIEF FOR RESPONDENT

I

STATEMENT OF THE CASE

This case arises upon a petition for the review of and to set aside an order to cease and desist issued by the Federal Trade Commission at the conclusion of proceedings on a complaint charging petitioner with engaging in unfair and deceptive acts and practices in violation of the Federal Trade Commission Act.[1]

The Commission complaint alleged that Carter Products, Inc.[2] (Carter) was engaged in the sale and distribution in

[1] The pertinent provisions of the Act are—

"Sec. 5(a)(1). . . . unfair or deceptive acts or practices in commerce, are hereby declared unlawful.

"Sec. 5(a)(6). The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations . . . from using . . . unfair or deceptive acts or practices in commerce (66 Stat. 632, 15 U.S.C. 45(a)(1), 45(a)(6).

[2] The complaint also named Street and Finney, a corporation engaged in the advertising business as respondent. The Commission dismissed the complaint as to this respondent.

commerce of a medicinal preparation known as "Carter's Little Liver Pills" (laxative pill), and had been making numerous false representations concerning this preparation which it sold throughout the United States. The complaint charged that such conduct constituted unfair and deceptive acts and practices in interstate commerce within the meaning of Section 5 of the Federal Trade Commission Act (R. 12940, Vol. I, 3-19).[3] Petitioner filed answer (id. at 21-29) in which it admitted its identity, the sale of the medicinal product and the dissemination of advertisements containing statements and representations as set forth in the complaint but the answer otherwise constituted a general denial.

After issue was joined, extended hearings were held before an examiner, beginning in November 1943 and ending in November 1945; 10,641 pages of testimony were taken and 2,209 exhibits were introduced. Upon the completion of the hearings, the examiner made his report to the Commission in July 1946 (R. 12940, Vol. I, 32-248), which contained a detailed and documented review of the evidence and the factual conclusions reached. Petitioner filed exceptions to this report (id. at 300) and the matter regularly came before the Commission for final disposition. The Commission considered the briefs filed and heard oral argument on the questions presented. Two Commissioners died and a third resigned before decision was reached and the case was reargued before the Commission after these vacancies had been filled. In March 1951 the Commission

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[3] This case was previously before the Court as No. 12940. It is now before the Court as No. 15373. The printed record in No. 12940 consisted of four volumes and these have been made a part of the present record. The additional parts of the record printed for this review, which consists of ten volumes, carry the case No. 15373.

Petitioner refers to the first four volumes using the citation O.R. and to the last ten under the designation N.R. We believe it more convenient to refer to the original printed record under the designation 12940 and the additional volumes under the designation 15373.

filed its findings of fact and conclusion (id. at 306) and issued a cease and desist order against this petitioner (Id. at 334).

Thereafter petitioner filed in this Court a petition for the review of the Commission's order (R. 12940, Vol. IV, 1681-1701) in which it did not then question the sufficiency of the evidence or the merits of the Commission's decision. The principal claim made was that petitioner had been denied a fair hearing in that the examiner had prejudicially restricted petitioner's cross examination of certain of the Commission's expert witnesses. This Court ruled (201 F.2d 446) that there had been "unjustifiable" restriction on cross examination of three such witnesses (Drs. Bollman, Lockwood and Case), and that the "cumulative" effect had operated to deprive petitioner of a fair hearing. The Court refused to consider whether there was other evidence ample to sustain the Commission's findings and orders so that the "unjustifiable" restrictions on cross examination were not actually prejudicial. The opinion concluded: "The order of the Commission is set aside."

The judgment entered by the Court provided that the Commission's order "be, and hereby is, set aside" (R. 15373, Vol. I, 25). A petition for rehearing alleged that error had been committed in failing to remand the case to the Commission to permit it to correct the errors which had been held to be prejudicial. The petition also alleged error in setting aside the order in its entirety, although the rulings which had been condemned did not affect in any respect numerous misrepresentations found by the Commission and severable parts of its order based thereon. This petition the Court denied without opinion (Id. at 26).

On petition for writ of certiorari the Supreme Court in a per curiam opinion (346 U. S. 327) granted the petition and at the same time vacated the judgment remanding the case with directions to this Court "to reinstate its prior judgment and order after amending it so that it specifically authorizes the Federal Trade Commission to open this

proceeding for further evidence and a new order consistent with the Court of Appeals' opinion herein." (R. 15373, Vol. I, 26-28).

Acting pursuant to the mandate of the Supreme Court this Court (on November 18, 1953) entered judgment in which it granted the petition to review and remanded the cause to the Commission with authorization "to open this proceeding for further evidence and a new order consistent with the opinion of this court" (R. 15373, Vol. I, 29-30). Thereafter the Commission entered an order reopening the proceeding and referred it to the hearing examiner "for such further proceedings as may be necessary to correct the errors in the original hearings as specified by the Court of Appeals" and ordered the examiner upon completion of the hearings to file with the Commission "a report upon the additional evidence and state the changes, if any, he wishes to make in his original recommended decision as a result of his consideration of such additional evidence." (Id. at 30).

Pursuant to this order, hearings were held at which Drs. Case and Bollman, two of the three expert witnesses, whose cross examination this Court held had been improperly curtailed and restricted, were tendered to petitioner for further cross examination.[4]

The cross examination of these witnesses was completed on April 30, 1954, and on June 25, 1954, petitioner filed a document containing motions and offers of proof (R. 15373, Vol. I, 33-56). One of these motions was to strike the testimony of Dr. John Salem Lockwood, which the examiner granted on February 9, 1955, and on March 3, 1955, entered an order closing the record for the reception of further evidence (Id. at 120-146).

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[4] Because of death, the third witness, Dr. Lockwood, whose cross-examination this Court held had been unduly restricted, could not be tendered for cross-examination. All of the testimony and all exhibits based upon or connected with the testimony of Dr. Lockwood were stricken by the examiner (R. 15373, Vol. I, 125).

On March 9, 1955, petitioner filed a notice of appeal from the order of the examiner closing the record and from his rulings denying petitioner's motions and offers of proof. Thereafter on March 28, 1955, petitioner filed a motion to disqualify the hearing examiner from taking any further action in this matter and for an order terminating these proceedings because of bias of the examiner. (R. 15373, Vol. I, 146-147).

On March 31, 1955, pursuant to the order of remand, the examiner filed his supplemental report and his recommendation as directed by the Commission (R. 15373, Vol. I, 173-199).

On September 20, 1955, the Commission entered an order denying petitioner's motion to disqualify the examiner and to terminate the proceedings (R. 15373, Vol. I, 245-256).

After obtaining from the Commission extensions of time for filing exceptions to the supplemental report of the examiner and its brief in support thereof, petitioner on November 30, 1955, filed its exception to the examiner's original and supplemental reports (R. 15373, Vol. II, 257-264; Vol. IX, 3557).

Thereafter the matter was heard by the Commission on briefs and oral argument. The Commission made its findings as to the facts (R. 15373, Vol. I, 267-310), and concluded (id. at 310) that the acts and practices of petitioners as found constituted unfair and deceptive acts and practices in violation of the Federal Trade Commission Act and issued its order to cease and desist (Id. at 311).

Petitioner thereafter timely filed its petition for review (R. 15373, Vol. VIII, 3531-3539) and its statement of points relied upon (id. at 3540), alleging numerous errors as having been committed by the Commission.

THE FACTS

We are here concerned with a simple laxative preparation and numerous representations made in connection with it. The record is large and voluminous, but it is important to notice that the actual area of factual conflict relates simply

and solely to what influence, if any, petitioner's laxative pill will have on the production and flow of bile. There are many facts in this case not involving this subject which are not in dispute. We shall summarize the facts with appropriate record citations and appropriate notation of the area of controversy.

Carter Products, Inc. is a Maryland corporation with its office and principal place of business located in New York. It has for many years been engaged in the sale and distribution in commerce of a medical preparation known as "Carter's Little Liver Pills" (R. 15373, Vol. I, 267-268).

The Commission found (R. 15373, Vol. I, 271-272) and it is not disputed that the quantitative formula for this medicinal preparation is:

Podophyllum Resin U.S.P. 1/16 gr.
Po. Purified Aloes ¼ gr.

The Commission also found (R. 15373, Vol. I, 272) on undisputed evidence that: "Podophyllum Resin, also known as podophyllum, is used as a laxative or drastic cathartic, and aloes is one of the irritant cathartics ranking with senna, rhubarb and cascara sagrada." This preparation, serves to increase temporarily the motility of the large bowel by irritation and thus induces partial evacuation of the large intestine (Id. 272).

The Commission found (R. 15373, Vol. I, 269-271) and it is not disputed that petitioner in connection with the sale of this laxative preparation had represented that it (1) represents a fundamental principle of nature in self-treatment; (2) is a competent and effective treatment for "a sluggish liver"; (3) will "wake up the flow of bile," is "effective in making bile flow freely"; (4) will cause the proper flow of gastric juices, vital digestive juices and vital alkaline juices; (5) is based on the fundamental principle of the operation of the digestive system, will "help food digestion," "lessen food decay," regulate digestion and the digestive system; (6) restore regularity, is a cure and

remedy and constitutes a competent and effective treatment for constipation; (7) will clear away the "dark clouds of listlessness and despondency" and "give one's personality a chance"; (8) will "keep up one's pep and vigor," "make one feel good and up to par again" and "keep one smiling and happy"; (9) will eliminate bad disposition and keep good dispositions "cheerful, happy and a regular thing"; (10) will help in more ways than one to make one feel better again fast and differently and will provide two-way relief; (11) follows nature's own order for regularity and so regulates the digestive process that if taken at night one will awaken feeling the way one wants to feel, "full of normal old-time pep and vigor," "alive," "alert," "cheerful," "peppy," "eager," "robust," "bright," "lively," "full of pep," "bounce," "energy," "springy," "snap," "go and vigor," "spry and chipper again," "perked up," "up on your toes," "up to snuff," "up to par again," "fit as a fiddle," "chipper-as-a-chipmunk," "on-top-of-the-world," "up and up," "rarin'-to-go," ready to "jump out" or "roll out" of bed, "singing like a lark," "singing a song for the sheer joy of living," "fresh as a daisy," "glad to be alive," "ready for a big breakfast"; (12) will influence the flow of liver bile so that one can overeat and overindulge without any discomfort and if one has overeaten or overindulged it will overcome such discomforts and enable one to wake up, "roll out of bed," "rosy and bright," "clear eyed and steady-nerved," "feeling just wonderful," "feeling like a million," free from that "blue-Monday feeling," "ready for a great big breakfast," "alert and ready for work"; (13) does not contain any strong medicine and is safe to use; (14) is a competent and effective treatment for some 70 mental and physical disorders set forth in Paragraph Seven of the complaint (R. 12940, Vol. I, 8-9); (15) will have therapeutic value in the treatment of disorders and diseases of the liver.

Upon consideration of the record the Commission found that the representations as summarized above and found to

have been made were misleading in material respects. It also found that through the use of the word "Liver" in the name "Carter's Little Liver Pills" petitioner had falsely represented that this preparation would have some therapeutic action, effect and influence on the liver, and is for use in the treatment of conditions, disorders, and diseases of the liver.

The Commission's finding as to the false and deceptive character of the representations made was based on its further findings that: "Inasmuch as the laxation afforded by an irritant laxative or cathartic is not a normal physiological method of evacuation and is not based on any principle having relation to natural bowel motility, it is not true that the preparation represents a fundamental principle of nature in self-treatment." (R. 15373, Vol. I, 272) This finding in turn was based on the evidence of the several doctors who testified: Dr. Ivy (R. 12940. Vol. II, 547); petitioner's witness, Dr. Lopez (id 896); petitioner's witness, Dr. Avrack (id 897); petitioner's witness, Dr. Whittemore (id 899); petitioner's witness, Dr. Leader (id Vol. III, 931); petitioner's witness, Dr. Dorman (id 932); petitioner's witness, Dr. Sanford (id 933, 934); petitioner's witness, Dr. Boyd (Id. 936).

The Commission also found (R. 15373. Vol. I, 272-273) that "In a scientific sense, constipation is a term used to connote a slower rate of evacuation of the large bowel than the one normal for that individual. Although it has reference to delay in the passage of indigestible residues through the alimentary tract and to infrequency of bowel action, and may be used to describe the condition in which the stools are dry and hard, constipation has been described also as being that condition which causes a person to believe that a cathartic is necessary to cause a bowel movement. Normal frequency in bowel movement varies widely among individuals. Because varied notions obtain with respect to what represents normal frequency, the average layman may not diagnose constipation properly and there

is a tendency for self-diagnosis to be made on the basis of symptoms having no relationship to constipation.

"In its chronic form, there are two general types of constipation: (1) spastic, and (2) atonic. The state of the musculature of the large bowel differs in the two conditions named. In the spastic variety, the musculature is abnormally contracted and rigid and does not propel the contents thereof forward in a normal manner. In the atonic condition, usually associated with an enlargement of the large bowel due to tremendously increased content, the musculature does not contract and retain its tonus or state of partial contraction. Atonic constipation is attributable to constitutional weakness of the muscles of the colon and is supposed to occur principally in the rectum, while the spastic type is supposed to be due principally to anxiety, worry, or nervous strain. Among the causes of constipation or irregularity of bowel movement are improper diet and stool habits, insufficient intake of fluids and variations or obstructions of the alimentary tract such as fissure, cancer and debilitating conditions. Factors predisposing to chronic constipation are numerous and thorough study by the physician is necessary before comprehensive treatment is undertaken. Its treatment, therefore, varies in individual cases, but is directed to correcting the basic conditions which are responsible." The several doctors who testified were in entire agreement on these fundamental propositions. (Dr. Carlson R. 15373; Vol. I, 399; Dr. Ivy R. 12940. Vol. II, 542-546; Dr. Palmer, id 692-693).

The Commission further found that with respect to the type of constipation known as spastic, petitioner's laxative pills "will tend to aggravate any state of spasticity which is present" (R. 15373. Vol. I, 274; see also R. 12940. Vol. I, 547). The Commission concluded therefore that any representation that the pills are a cure or remedy for and constitute a competent and effective treatment for constipation are false and misleading.

In this connection, the Commission further found (R.

15373; Vol. I, 274) on undisputed evidence that the habitual use of irritant laxatives and cathartics tends to produce irregularity rather than to restore regularity in cases of chronic constipation and the use of petitioner's preparation will not restore regularity of bowel movement (R. 12940; Vol. I, 287; R. 15373; Vol. II, 650; R. 12940; Vol. II, 695).

The Commission also found (R. 15373; Vol. I, 274) and it is not disputed, that the statements appearing in the advertising to the effect that petitioner's product is composed of two vegetable medicines and the references to "gentle action purportedly afforded by its use" (id 274); see also id. Vol. II, 648) imply that petitioner's laxative pills do not contain strong medicines.

The Commission found (R. 15373, Vol. I, 274) and the record shows, however, that petitioner's laxative pills do contain strong medicines. The Commission pointed out, and the record shows, that though the ingredients of these pills are obtained by purifications of members of the plant kingdom they are in fact irritant purgatives. The record shows that aloes taken in sufficient amounts lead to some hyperemia and increased vascularity. Neither aloes nor podophyllin is absorbed to any great extent and as long as they remain in the colon may cause local irritation.

The Commission also found and it is not disputed that the product is not safe for and harmless to all individuals who are constipated or suffering delay or irregularity of bowel movement and symptoms thereof or from failure of digestion. It was found and it is not disputed that the pills are potentially injurious if taken by persons suffering from abdominal pains, nausea, vomiting, or other symptoms of appendicitis (R. 15373; Vol. I, 274-275). It was found and it is not disputed that it may cause perforation of the intestine in instances where delay in the evacuation is due to obstruction in the tract. It was pointed out (id 275) that in some instances the use of these pills may be attended with griping and stomach discomfort and when used in the presence of constipation of the spastic type

may serve to increase and aggravate such state of spasticity (id 275). It found and the evidence is uncontradicted that the use of a laxative is contraindicated in many conditions.

The Commission also found (R.15373; Vol. I, 304-305) that the ingredients in this laxative neither alone nor in combination will have any therapeutic action, effect, or influence, corrective or otherwise, on the liver. The preparation will have no therapeutic value in the treatment of any condition, disorder, or disease of the liver or the biliary system. This finding was based on undisputed evidence of Doctors Carlson (R. 12940. Vol. I, 366), Ivy (id. Vol. II, 549) and Palmer (id 689-690.) Upon consideration of the remedy which should be applied under the circumstances the Commission was of the opinion (R.15373; Vol. I, 308) that only excision of the word "Liver" from the product name would serve to eliminate the deception engendered by its use.

The Commission also found (R. 15373, Vol. I, 303, 304) that these laxative pills will not increase the production and flow of bile. The present controversy centers in this area of the findings. The Commission witnesses, Doctors Carlson (R. 12940; Vol. I, 255-258, 376, 386), Palmer (id 284) and Ivy, (id. 267-270) uniformly testified that this laxative would have no effect on bile flow. Petitioner's witnesses included Doctors Hazelton, Morrison and Killian. Doctor Morrison testified on direct examination that this laxative would effect bile flow (R. 15373; Vol. III, 1071); Doctor Hazelton said his experiments would not permit a conclusion (R. 15373; Vol. II, 795) and Doctor Killian said that it would effect bile flow under conditions and his statement of those conditions essentially and practically negates the conclusion.

As to any possible effect the petitioner's laxative pill may have on the formation or flow of bile, the Commission in its findings considered the testimony and other evidence relating to experiments conducted by various scientists, offered in support of the complaint (R. 15373; Vol. I, 277-286), and of those offered by the petitioner (id 286-291); in addi-

tion, the Commission in its findings considered and weighed the challenges and criticisms made by petitioner of the various experiments performed by the scientists offered in support of the allegations of the complaint (id 292-299) as well as the criticisms and challenges made by counsel supporting the complaint as to the experiments performed by scientists offered on behalf of the petitioner. (id 299-302) The Commission in its findings also considered and weighed the expressions of scientific view by witnesses presented by the petitioner as to the effect "that a favorable influence on bile flow may result from the increased intestinal motility afforded by the irritating action of a laxative" of the same type as that of the petitioner (Id 302).

Then after all such considerations, the Commission found that "the greater weight of the testimony and other evidence introduced into the record supports informed determinations," that petitioner's laxative pills "will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver"; the Commission further found that petitioner's laxative pill will not increase the flow of bile or any constituents thereof into the duodenum (Id. 303-304).

CONTESTED ISSUES

In its brief (6-10) petitioner lists twelve specifications of alleged errors and summary of argument. In specifications 1 through 8, petitioner states that the findings are erroneous because of the alleged method and manner in which the Commission considered or failed to consider the testimony and other evidence relating to experiments and tests conducted by witnesses for the Commission and for petitioner. This evidence was admitted into the record as being responsive to the allegations in the complaint that petitioner's statement as to the effect of its laxative pill on bile was false and misleading. The findings referred to in petitioner's specifications must, therefore, relate to the

Commission's findings that petitioner's laxative pill will have no effect on the formation or flow of bile. That this is true is borne out by petitioner's argument in its brief. Petitioner develops its argument under three points. Under Points I and III, petitioner contends that there is no substantial evidence to support the findings of the Commission that its laxative pill will have no effect upon the formation or flow of bile. This is only one of the many findings of fact made by the Commission relating to the falsity of petitioner's statement as to the therapeutic value of its laxative pill. Point II is based upon petitioner's contention that it was denied a fair and impartial hearing.

We therefore believe that the only issues raised before this Court are:

1. Whether the findings that petitioner's laxative pill will have no effect on the formation or flow of bile is supported by the greater weight of the evidence?, and
2. Whether petitioner was denied a fair and impartial hearing?

III

ARGUMENT

Preliminary Statement

(1) In view of the voluminous record and the lengthy briefs we believe it is important that attention be focused on the actual area of controversy. It must be appreciated that in the proceedings before the Commission there was at issue the truth or falsity of numerous representations concerning the therapeutic value of this pill admittedly sold only as a laxative and admittedly containing only two active drugs—aloes and podophyllum—both recognized as irritative laxatives.

While there appears to have been a general charge made in the petition for review that the findings were not supported by substantial evidence, examination of petitioner's

brief discloses that the actual area of attack is very limited. As we understand petitioner's contentions they relate only to those findings regarding the flow of bile. This court cannot be "compelled to search the record for undesignated error" claimed upon an omnibus assertion that the findings are unwarranted. *North Whittier Heights Citrus Ass'n.* v. *National Labor Relations Board,* 109 F.2d 76, 83 (C.A. 9, 1940), cert. denied 310 U.S. 632 (1940). The rules[5] of this Court and established precedents demonstrate that it is only the particular findings attacked which are to be considered by the Court on review. See, *Dayton Rubber Mfg. Co. of Delaware* v. *Sabra, et al.,* 63 F. 2d 866 (C.A. 9, 1933); *Mutual Life Ins. Co. of New York* v. *Wells Fargo Bank & Trust Co.,* 86 F.2d 585, 587 (C.A. 9, 1936); *Smith* v. *Hopkins,* 120 F. 921, 923 (C.A. 7, 1902).

Under the circumstances, therefore, we submit that regardless of what this Court's decision may be on this particular issue of fact raised by petitioner, NEVERTHELESS, the Commission is entitled to and the Court should enter a decree (1) affirming all other findings of fact, and (2) enforcing Subsections (a), (b), (c,) (d), (e), that portion of (f) which reads: " . . . or to prevent or overcome discomforts caused by overindulgence in food or other pleasures," (g), (h), (i), (j), (k), (l), (m), (n), (o) of Paragraph (1) and Paragraph (2) of the order to cease and desist.

(2) In considering the vigorous and sustained attack made by petitioner on the Commission's expert witnesses we believe it is important to invite the Court's attention to the many basic facts which are not really the subject of any dispute and which necessarily must be considered in evaluating the numerous claims made by the petitioner. Thus

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[5] Subsection 2(d) of Rule 18 of the Rules of this Court, among other things, provides: ". . . In all cases, when findings are specified as error, the specification shall state as particularly as may be wherein the findings of fact and conclusions of law are alleged to be erroneous."

it appears that petitioner's own expert witnesses[6] testified that laxatives, such as petitioner's laxative pill, are prescribed solely for the temporary relief afforded by the evacuation of the bowels.

Petitioner's pill is a laxative. The qualitative and quantitative formula is Podophyllum Resin USP 1/15 Gr., PO Purified Aloes, ¼ Gr. (CXs. 4-B, 5-B). Aloes is classified as one of the irritant laxatives and podophyllum is a drastic cathartic (R. 12940, Vol. II, 552). Podophyllum has been removed from the U. S. Pharmacopeia (id. Vol. IV, 1337-1338). These two drugs are "vegetable drugs" as they are obtained from some member of the plant kingdom. They are not vegetables in the sense that they can be eaten (id. Vol. II, 556, 684). The two drugs contained in petitioner's laxative pill have no different action when taken separately. (R. 15373, Vol. I, 359-360; Vol. II, 685; Vol. IV, 1572); and they have no synergistic effect. (R. 15373, Vol. II, 503-504; R. 12940, Vol. II, 884; Vol. IV, 1572-1573; R. 15373, Vol. I, 427-429).

Bile is partly a secretion and partly an excretion of the liver. A normal liver which is not diseased will produce the amount of bile normally required for the proper function of the digestive system (R. 15373, Vol. I, 407-408; R. 12940, Vol. II, 530). The function of bile in the human digestive system is the emulsification of fat in the food and the absorption of such fat and fat soluble vitamins (R. 15373, Vol. I, 368-369, 371-372; Vol. II, 478-479, 475-476). The chief characteristics of bile are bile acids, bile pigments, fatty acids and cholsterol. The basic ingredients of bile are bile salts or bile acids (id. Vol. I, at 371-373; Vol. VII, 2918; R. 12940, Vol. II, 532). The facilitating of the

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[6] Drs. Harry Julius Johnson, Abbott W. Allen, Joseph Jordan Eller, Walter Ralph Loewe, Rafael Ernesto Lopez, James S. Edlin, John Albert Averack, W. Laurance Whittemore, Frederick Steigmann, Leonard Owen Leader, Duane D. Daling, Henry P. Dorman, William C. Colbert, Louis F. Boyd (R. 12940, Vol. II, 879-883, 896-898, 899-901; Vol. III, 929-936, R. 15373, Vol. II, 831; Vol. III, 942-946).

digestion and absorption of fat is the sole function of bile. It has no effect upon the digestion of proteins (R. 15373, Vol. I, 372, 375). If there is an impairment or a disease of the liver which cuts the production of bile to 80% there still would remain sufficient bile for the proper digestion of fat food (R. 12940, Vol. IV, 1417-1418, 1478). An individual does not require the production of two pints of bile daily to prevent digestive disturbances (Id. Vol. II, 671-674, 1557).

We believe it is equally important to invite the Court's attention to the fact that there is no evidence of any nature in the record that any doctor has ever prescribed petitioner's laxative pill for any purpose other than to produce an evacuation of the bowels.

There is no evidence of any nature in the record that this laxative pill of petitioner *when taken as directed* will have any effect upon the formation secretion or flow of bile. And there is no evidence of any nature in the record that this laxative pill of petitioner *when taken as directed* will have any effect upon any disease or disorder of the liver.

(3) Petitioner suggests (Pet. Br. 151-152) that since this proceeding started many years ago there is no present need for an order to cease and desist. But we invite the Court's attention to the fact that there is no evidence or in fact any statement which would show that petitioner has discontinued the advertising statements found to be false and misleading and which furnish the basis for the order to cease and desist. Certainly petitioner cannot by a mere unsupported "suggestion" make any valid claim as to discontinuance. *Marlene's Inc.* v. *Federal Trade Commission,* 216 F. 2d 556 (C. A. 7, 1954). In fact its whole position in this regard is suspect since it is still contesting the validity of the Commission's order. But despite that, there is simply no evidence in this recard that the testimony, experiments and other evidence upon which the Commission based its findings is not presently valid, up to date, and applicable.

(4) Consideration of petitioner's brief convinces us that

it is replete with inaccuracies and misconceptions of the record. In our opinion petitioner's brief presents a distorted version of the testimony and experiments of the expert witnesses who testified in the proceeding. We are convinced that petitioner's brief contains many misstatements of fact and that it would be impossible to prepare a detailed reply to each and every misstatement and therefore we shall undertake to point out certain of the distortions and misstatements which we consider illustrative of the type set forth in the brief filed by petitioner. For example: On page 15 of its brief, petitioner emphasizes, and quotes out of context, portions of two statements made by Dr. Ivy and applies these statements to the fistula dog experiments performed by Dr. Ivy. Petitioner then contends that prior to Dr. Ivy's retention by the Commission to perform these tests and "when he had . . . no motive or bias to subserve," Dr. Ivy admitted that an inherent vice existed in this type of experiment because "the physical conditions are entirely changed" and there is produced thereby "a disturbance and possible creation of abnormal difference in pressure."

In an effort to bolster and clothe this contention with a semblance of truth, petitioner reaches into the testimony of Dr. Carlson, and states that his testimony supplied "the common sense reason for this basic fallacy in such test methods . . ."; that Dr. Carlson (1) "swore . . . that if the bile does not flow into the intestines in the normal way, this has both a 'back' and a 'bad' effect upon the liver," and (2) "that all the various units of the biliary system must be operating normally in order for the experiments to be valid." Petitioner here flatly tells this Court that when Dr. Carlson so testified he was specifically referring to the fistula test methods as performed by Dr. Ivy.

An examination of this testimony of Dr. Ivy and Dr. Carlson will show, however, that petitioner has diverted this testimony from its true and intended meaning and misapplied it to the experiments performed by Dr. Ivy in

an effort to show that the fistula method experiments were basically unsound, worthless and of no scientific value[7] so as to destroy the impact of the results obtained by Dr. Ivy upon petitioner's claims as to the therapeutic value of its laxative pills.

When Dr. Ivy was being cross examined (R. 15373, Vol. II, 683-684), counsel asked him if he thought that the manner in which he had prepared the dogs for his experiments "produced any physiological or pathological changes of any kind in the animals." Dr. Ivy asked counsel, "What do you mean abnormal or pathological cases [sic]? What do you refer to?" Counsel then read the following statement—which appeared in an article that Dr. Ivy had previously identified (R. 12940, Vol. II, 708) as having been written by him entitled "Physiology of the Gall Bladder," published in "Physiology Reviews" in 1934—

> But with a duodenal tube in place or with a duodenal or common duct fistula, the physical conditions are entirely changed, a fact that has been disregarded too frequently.

and asked Dr. Ivy, "What do you mean by that statement?" Dr. Ivy replied that he would "have to see the context." After reading the article Dr. Ivy said:

> Now, the sentence that the attorney just read is a sentence in a discussion of the question "Is the force of contraction of the gall bladder sufficient to force bile into and through the cystic duct?" "Intrinsic ability of the gall bladder to evacuate." And under a separate head, "Intra-abdominal pressure."
>
> And that sentence simply indicates that when there is a duodenal tube in the duodenum, it means that the

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[7] The record establishes the fact and it is not contradicted by any testimony of any witness that the biliary fistula method experiments as performed by Dr. Ivy are accepted and officially recognized as a proper method to be used in laboratory experiments on the formation and flow of bile. See ante p. 32.

> duodenal pressure communicates with the atmospheric pressure on the outside of the abdomen and that is all that statement refers to. If you don't have a tube down the duodenum, under ordinary conditions, the pressure in the duodenum does not reflect the pressure on the outside.

Counsel then asked Dr. Ivy, "Well what about your reference to the 'common duct fistula?'" To which Dr. Ivy replied:

> The same thing is true. The pressure on the outside opens into the common duct. The situation is the same—just a disturbance and of possible creation of abnormal difference in pressure.

(R. 15373, Vol. II, 683-685). Dr. Ivy was explaining that the sentence referred to by counsel simply indicated that when a duodenal tube was inserted in the duodenum the normal pressure of the duodenum was affected by the atmospheric pressure, resulting in a change, a difference of pressure in the duodenum. This testimony has nothing whatever to do with the correctness of the methods used by Dr. Ivy in his fistula dog experiments and it is not a pronouncement or a flat concession that there was an inherent vice in the experiments performed by him on the fistula dogs. There is no language in that testimony from which a normal, logical inference can be drawn that the fistula dog experiments contain "fatal infirmities" as petitioner would have this Court believe.

Now let us examine the testimony of Dr. Carlson, which petitioner refers to as supplying the common sense reason for the alleged basic fallacy in Dr. Ivy's tests. Dr. Carlson was being questioned as to his experiments with the digestive and hepatic systems (R. 15373, Vol. I, 343-345), and was asked what experiments he had made on the hepatic system, Dr. Carlson replied:

> I have studied the machinery of the emptying of the gall bladder, and I have made some studies of the back effect on the liver by obstruction of the bile passage, so that the bile secreted cannot flow into the intestines.

When Dr. Carlson was asked to explain what he meant by the statement "back effect on the liver," he replied:

> What I mean by that is this, that the liver itself may be perfectly normal. Then you get a stone in the common duct, or you may get catarrah. You may get it filled with mucus or you may get cancer obstructing the duct. Then that secretion of bile extends the duct. *It does not get into the intestine in the normal way,* and that has a bad effect in the way of injuring the liver. (Emphasis supplied)

Here Dr. Carlson was testifying to conditions which completely obstruct the normal flow of bile from the liver, which resulted in the bile backing up into the bile duct of the liver thus causing injury to the liver. This testimony of Dr. Carlson had nothing whatever to do with the fistula dog experiments conducted by Dr. Ivy as petitioner would suggest. Petitioner should know that in the fistula dog experiments there was no obstruction of the flow of bile at any time in either the duodenal tube draining or the T-tube drainage method; that the bile flowed freely from the common duct of the liver into the tubes and outside into a bag or a cylinder and there collected. And yet, petitioner flatly tells this Court that this testimony of Dr. Carlson in reference to the obstruction of the common duct of the liver by cancer, stone, catarrah and mucus, preventing completely any flow of bile, applies squarely to the tests performed by Dr. Ivy. We respectfully submit that petitioner here is being something less than candid with this Court.

In addition, petitioner, referring to the testimony of

Dr. Carlson (R. 12940, Vol. II, 481-482), states that Dr. Carlson swore "that all the various units of the biliary system must be operating normally in order for the experiments to be valid." There is no such statement made by Dr. Carlson in the testimony referred to. After Dr. Carlson had testified (1) as to the effect upon the digestive system of a decrease of fifty per cent in the normal flow of bile, (2) that an individual normally has more bile than needed, (3) that there are certain diseases of, and injuries to, the liver that decreases the production of bile, (4) that obstructive disturbances of the duct and bladder and sphincter system causing the retention of bile, Dr. Carlson was asked, "In other words, the various parts or units of the biliary system, such as the liver, the gall bladder, the ducts, and the sphincter must all operate normally, or the machine is thrown out of gear is that about right?" Dr. Carlson replied: "That would be a fair statement, but in degree. The machine is thrown out of gear even if we have twenty-five per cent reduction in the production of bile from the liver, but that doesn't necessarily mean that the machinery of digestion of fat is thrown off, because we don't need all the bile, normal bile for the digestion of fat."

It is apparent from the above that Dr. Carlson was not referring in any way to the fistula dog experiments conducted by Dr. Ivy; and that his testimony as to the biliary system operating normally in no way relates to the validity or invalidity of the experiments conducted by Dr. Ivy.

In addition to the above questionable statements appearing on this one page of petitioner's brief (p. 15), petitioner also attempts to discredit the testimony of Dr. Ivy. Petitioner tells the Court that the statement of Dr. Ivy "of the inherent vice in his animal tests . . . was made . . . before his retention by the Commission to perform these experiments in this case and at a time when he had accordingly no motive or bias to subserve." Petitioner is here telling the Court that Dr. Ivy was retained by the Com-

mission to perform these experiments. This statement is made out of the whole cloth. There is not one vestige of truth in it.

Petitioner throughout its brief (i.e., pp. 69, 78) improperly claims that Dr. Ivy had written an article to the effect that there is a causal relationship between constipation and bile flow. When questioned about that particular article by petitioner's counsel, Dr. Ivy said that he had "found that distention of the entire colon was associated with an inhibition of bile flow in 12 out of 14 dogs." He reminded counsel, "that was acute distention. It lasted only for a period of 5 or 10 minutes" (R. 12940, Vol. II, 707). Dr. Ivy also said: ". . . Acute distention does not have a marked inhibitory effect on the formation of bile, so that you can easily counteract it, in other words, by giving some sodium dehydrochloate" (id. at 709). Dr. Ivy explained that human beings with a "cathartic colon" have a condition "which would be analogous to the type of condition we were trying to produce in the dog and monkey" (id. at 712; id. Vol. IV, 1567). When Dr. Ivy was asked if there was any connection in the creation or flow of bile and constipation, he said "No, there is none . . ." (id. Vol. II, 541).

In its brief (p. 69) petitioner makes a further attempt to make a false impression as to Dr. Ivy's views concerning constipation and bile flow. Dr. Ivy testified that a complete lack of bile "would be called a predisposing factor" in constipation. When asked if constipation did result "would the constipation be likely to increase the tendency toward lack of bile?," Dr. Ivy replied: "No" (R. 12940, Vol. II, 714). Dr. Ivy went on to say that his article entitled "The Rationale on Bile Salts Therapy" was to the same effect (id. at 715).

Petitioner also attempts to cite the duodenal drainages that Dr. Ivy performed on "constipated" human beings and jejunal fistula dogs as evidence that Dr. Ivy regards the duodenal drainage method as proper to test the

efficacy of petitioner's laxative pills. Dr. Ivy explained that although he did not think the duodenal drainage method was reliable, he used it in his experiments for the purpose of completing his series of studies. He said: "For quantitative work, the duodenal or the method of duodenal drainage is very unreliable . . ." He continued and said, "We have obtained no evidence to show that [petitioner's laxative pills] promote the flow of bile into the duodenum" (R. 12940, Vol. IV, 1538-1539).

Perhaps one of the worst examples of distortion indulged in by petitioner in its brief appears on page 150 in which it states that Dr. Bollman testified, ". . . one would have to devise better tests than we have now in order to ascribe a significant difference to minor changes in the correlation of the flow of bile." Petitioner quotes only a part of a sentence in Dr. Bollman's testimony. What Dr. Bollman actually said was: "One would have to devise better tests than we have now in order to ascribe a significant difference in minor changes in the correlation of the flow of bile *with the condition of the liver as judged by hystologic examination or in comparison with other tests* (R. 12940, Vol. IV, 1496). Petitioner omitted the italicized portion of Dr. Bollman's testimony. Dr. Bollman was testifying on whether anesthetics would diminish the bile flow and as to the correlation of the flow of bile with the condition of the liver following the giving of an anesthetic. He testified that in the light of present knowledge the diminution of bile flow following the giving of an anesthetic would not be of any significance. He explained this by saying, "I would expect the effect of ether to cause diminution in the rate of bile flow during the time of ether anesthesia and perhaps continuing, perhaps 2 or 3 hours after recovery from the ether—at the end of that time the animals would revert to normal and the bile flow would be the same as normal" (R. 15373, Vol. VIII, 3456). The experiments of Dr. Bollman on the dogs (CXs 195-A, B and C) required from 7 to 35 days for their completion and

the fact that perhaps for 2 or 3 hours after the ether was administered there might have been diminution of bile flow could not have any influence on the results of the experiments for the reason that the dogs' livers after the 2 or 3 hours had thrown off the effect of the anesthesia and were functioning normally. Petitioner's statement (Br. 150) that Dr. Bollman had testified as to "the inadequacy and lack of significant sensitivity" of the "liver function tests" used by him in his dog experiments is without foundation and a complete distortion of Dr. Bollman's testimony.

This brings us now to a consideration of the evidence in this record upon which the Commission based its finding that petitioner's laxative pill will have no effect on bile.

1. The Finding That Petitioner's Laxative Pill Will Not Increase the Flow of Bile Is Supported by the Greater Weight of the Substantial Evidence.

The applicable law in this case is well settled. Except as to the issue of a fair and impartial hearing, the sole issue of fact developed by petitioner and properly before this Court relates to the effect of petitioner's laxative pill on bile. The Commission is the trier of the facts. And its finding here that this laxative pill will have no effect on bile is a finding of fact which is conclusive and binding on this Court if supported by substantial evidence. The statute so provides.[8] This Court has often so held.[9] Whether a witness possesses the requisite qualification as an expert and whether tests were properly conducted are also questions of fact to be determined by the Commission,

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[8] Federal Trade Commission Act, § 5(c); 52 Stat. 113; 15 U.S.C. 45(c); *Federal Trade Commission* v. *Standard Education Society, et al.*, 302 U.S. 112, 117 (1937).

[9] *Jacques De Gorter and Suze C. De Gorter, etc.* v. *Federal Trade Commission*, 244 F. 2d 270 (C.A. 9, 1957); *Philip R. Park, Inc.* v. *Federal Trade Commission*, 136 F. 2d 428, 429 (C.A. 9, 1943); *American Medicinal Products, Inc.* v. *Federal Trade Commission*, 136 F. 2d 426 (C.A. 9, 1943).

and such determination is conclusive unless palpably wrong, *Leach* v. *Carlile,* 258 U. S. 138, 139-140 (1922).

Opinion evidence based on the general medical and pharmacological knowledge of qualified experts constitutes substantial evidence, even if the experts have no personal experience with the product, *Goodwin* v. *United States,* 2 F. 2d 200, 201 (C. A. 6, 1924); *Dr. W. B. Caldwell Inc.* v. *Federal Trade Commission,* 111 F. 2d 889, 891 (C. A. 7, 1940); and this is true even where witnesses who had personally observed the effects of the product testified to the contrary, *John J. Fulton Co.* v. *Federal Trade Commission,* 130 F. 2d 85, 86 (C. A. 9, 1942); *Bristol-Myers Co.* v. *Federal Trade Commission,* 185 F. 2d 58, 62 (C. A. 4, 1950; *Justin Haynes & Co.* v. *Federal Trade Commission,* 105 F. 2d 988, 989 (C. A. 2, 1939); *Neff* v. *Federal Trade Commission,* 117 F. 2d 495, 497 (C. A. 4, 1941); *J. E. Todd, Inc.* v. *Federal Trade Commission,* 145 F. 2d 858 (C. A. D. C., 1944).

It is too well settled to require argument that it is for the Commission and not the Courts to pass upon the credibility of witnesses and the weight to be accorded their testimony, and this Court has so held, *Tractor Training Service, et al.* v. *Federal Trade Commission,* 227 F. 2d 420, 424 (C. A. 9, 1955). Also see *Corn Products Refining Co., et al.* v. *Federal Trade Commission,* 324 U. S. 726 (1945); *Federal Trade Commission* v. *Standard Education Society, et al.,* 302 U. S. 112, 117 (1937); *Standard Distributors, Inc., et al.* v. *Federal Trade Commission,* 211 F. 2d 7, 12 (C. A. 2, 1954); *P. Lorillard Co.* v. *Federal Trade Commission,* 186 F. 2d 52, 57 (C. A. 4, 1950).

It is well settled that the "weight to be given to the facts and circumstances admitted as well as inferences reasonably to be drawn" therefrom are for the Commission, *Federal Trade Commission* v. *Pacific States Paper Trade Assn.,* 273 U. S. 52, 63 (1927), and the "possibility of drawing either of two inconsistent inferences from the evidence" does not prevent the Commission from draw-

ing one of them, *National Labor Relations Board* v. *Nevada Consolidated Copper Corp.*, 316 U. S. 105, 106 (1942).

It is also well settled that courts of appeals must not "pick and choose bits of evidence to make findings of fact contrary to the findings of the Commission," *Federal Trade Commission* v. *Standard Education Society, et al.*, 302 U. S. 112, 117 (1937). Inferences of fact drawn by administrative agencies "may not be set aside upon judicial review because the courts would have drawn a different inference," *National Labor Relations Board* v. *Southern Bell Telephone Co.*, 319 U. S. 50, 60 (1943); *National Labor Relations Board* v. *Nevada Consolidated Copper Corp.*, 316 U. S. 105, 106-107 (1942).

In reviewing the decision of administrative agencies, the courts are to "consider the whole record." But "the requirement for canvassing 'the whole record' in order to ascertain substantiality" was not "intended to negative the functions of . . . those agencies presumably equipped or informed by experience to deal with the specialized field of knowledge whose findings within their field carry the authority of an expertness which courts do not possess and therefore must respect. Nor does it mean that even as to matters not requiring expertise a court may displace [an agency's] choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo." *Universal Camera Corp.* v. *National Labor Relations Board*, 340 U. S. 474, 487-488 (1951).

The Supreme Court has also declared that the Commission was created with the avowed purpose of resting the administrative functions committed to it in a body of experts specially competent to deal with them, *Humphrey's Executor* v. *United States*, 295 U. S. 602, 621, 625 (1935). It is "not the province of the court to absorb the administrative functions to such an extent that the executive or legislative agencies become mere fact finding bodies." *Gray* v. *Powell*, 314 U.S. 402, 412 (1941).

In a proceeding of this nature the power of this Court is not administrative but judicial and "the range of issues open to review is narrow. Only the questions affecting the Constitutional power, statutory authority and the basic prerequisites of proof can be raised. If these legal tests are satisfied, the Commission's order becomes incontestible," and "judicial function is exhausted when there is found to be a rational basis for the conclusions approved by the Administrative body." *Dobson* v. *Commissioner of Internal Revenue,* 320 U. S. 489, 501 (1943).

The above applicable principles of law have neither been limited nor restricted by the Administrative Procedure Act. The Administrative Procedure Act (60 Stat. 243-244, 5 U. S. C. 1009(e)) provides that administrative agencies should make their findings on the whole record "taking into account contradictory evidence or evidence from which conflicting inferences could be drawn." This Court speaking through District Judge Yankwich in the De Gorter case, 244 F. 2d 270, 272-273 (C. A. 9, 1957), had this to say:

> The enactment of the Administrative Procedure Act has placed upon the Courts the responsibility of reviewing the entire record with the object of determining whether, on the whole, substantial evidence sustained the action of the administrative body. This means that
>
> ". . . the findings are to be accepted unless they are unsupported by substantial evidence on the record considered as whole."

So doing, Courts will not substitute their judgment for that of the Commission. As stated by the Court of Appeals for the Second Circuit recently,

> "It was for it, not for us, to pass upon the credibility of the witnesses and the weight to be given their testimony in the light of it; conflicting or other-

wise . . . having done so, the findings of the Commission, when, as here, the record as a whole gives them substantial support, are final *even though the evidence is so conflicting that it might have supported the contrary had such* findings been made." [10]

Bearing those well settled and applicable principles of law in mind, we now turn to the record and examine the evidence upon which the Commission based its findings that petitioner's laxative pill will not increase bile flow.

a. Petitioner's Laxative Pill Will Have No Effect Upon the Formation or Flow of Bile

The complaint alleged (Par. Nine; Vol. I, 11-15) that petitioner's laxative pill "will not wake up the flow of bile . . . is not effective in making bile flow freely . . . will not influence the production or flow of liver bile . . . will have no therapeutic action, effect or influence on the secretion or flow of bile . . ."

The Commission found (Par. Fourteen, R. 15373, Vol. I, 303-304) ". . . that the greater weight of the testimony and other evidence introduced into the record supports informed determinations that [petitioner's laxative pill] will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver. Inasmuch as the evidence further shows that [petitioner's] product will not cause the gall bladder to contract or cause laxation of the sphincter of Oddi or prevent its contraction in the first instance or serve in any way to milk bile from the ampula of Vater or the bile duct, the Commission further concludes that [petitioner's laxative pill] will not increase the flow of bile or any constituents thereof into the duodenum."

Petitioner attacks this finding on the ground that the evidence relied upon is insubstantial because the witnesses whose testimony the Commission relied upon, were

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[10] See also *Tractor Training Service* v. *Federal Trade Commission*, 227 F. 2d 420, 424-425 (C.A. 9, 1955).

biased and prejudiced and because the experiments upon which the Commission relied were defective and not properly conducted. Petitioner's entire argument in support of its contention relates to the credibility of the witnesses and the weight to be accorded their testimony and the legality of the experiments in connection therewith.

This Court has often held that it is for the Commission and not the courts to pass upon the credibility of witnesses and the weight to be accorded their testimony (see supra, p. 25). Whether the experiments relied upon by the Commission were properly conducted or legal is a question of fact and like all questions of fact is to be determined by the Commission and such determination is conclusive unless palpably wrong (see supra, pp. 24-25).

The finding of the Commission here is based upon opinion evidence expressed by expert witnesses which is undenied and uncontradicted, and upon the results of tests and experiments conducted by experts.

Dr. Andrew J. Carlson, one of the greatest physiologists in the world, testified that petitioner's laxative pill will have "no effect whatever on secretion and the flow of bile in health or in diseases" (R. 12940, Vol. I, 386).

Dr. Walter L. Palmer, a member of the faculty of the University of Chicago Medical School, testified that the concensus of competent, informed medical opinion was that the drugs, aloes and podophyllum, constituents of petitioner's laxative pill, will not increase the production or flow of bile (R. 12940, Vol. II, 696-697).

Dr. Andrew C. Ivy, Head of the Division of Physiology, Pharmacology, Materia Medica and Toxicology of Northwestern University; Director of the Naval Medical Research Institute of Bethesda, Maryland, testified that in his opinion petitioner's laxative pill will have no effect on the formation and flow of bile or bile salts (R. 12940, Vol. II, 533).

In addition to this uncontradicted opinion testimony, the record contains experiments made by scientists in an

effort to find what effect petitioner's laxative pill would have upon the formation and flow of bile. These experiments were performed by Dr. Ivy, Dr. Bollman and Dr. Case.

i. Experiments Performed by Dr. Ivy to Determine if Petitioner's Laxative Pill Will Have Any Effect Upon the Formation of Bile by the Liver

For the purpose of determining whether or not the drugs contained in petitioner's laxative pill (aloes and podophyllum) would have any effect upon the formation of bile by the liver, Dr. Ivy performed certain experiments on dogs (see CX 97). The dogs were given ether, their gall bladders removed and a catheter inserted in their cystic ducts, their common bile ducts cut so that all of the bile formed by the liver flowed out through the catheter into a bag or cylinder from which it was removed, measured and analyzed. This type of experiment is known as biliary fistula.

We might note here petitioner's attempt (Br. p. 14) to lead the Court to believe that the anesthetics used on the dogs would abolish or exempt the flow of bile while the experiments were being conducted. This is not a fact. Dr. Ivy testified (R. 12940, Vol. II, 716) that none of these dogs were used until the effect of the ether had worn out and their livers were functioning normally. Dr. Herman Annegers, one of petitioner's witnesses, who assisted Dr. Ivy in these experiments, stated that no dog was used until they were certain that the dog was normal and putting out a constant volume of bile (R. 12940, Vol. II, 910-911).

Eleven experiments (CX 97; R. 12940, Vol. II, 575-579) were performed on 5 dogs thus prepared. A controlled period of 2 or 3 days was run on the dogs during which time the dogs were fed a weighed amount of standard diet. The bile was collected, measured and analyzed at the end of each 24 hours. After the control period a test period of 2 or 3 days was run, during which time the animals were fed the same standard diet but in addition were given a capsule containing a mixture of aloes and podophyllum

in an amount equivalent to that found in 3 of petitioner's laxative pills. The bile was collected, measured and analyzed every 24 hours. The bile collected during the controlled period and the bile collected during the test period were compared.

For the purpose of comparing the effect on the secretion of bile where bile salts only were given, and where bile salts plus a mixture of aloes and podophyllum equivalent to that found in 2½ petitioner's laxative pills is given, 8 additional experiments were performed on 2 dogs (CX 97, p. 2). With the dogs prepared in the same manner as in the first experiment, controlled tests were run for 2 or 3 days, during which time the dogs were fed the regular diet only, the bile collected and analyzed every 24 hours. Then a test period of 2 or 3 days was run. The dogs were fed the regular diet daily with 3 grams of bile sales added, the bile collected and analyzed every 24 hours. Then for another 3 days the dogs were fed the regular diet daily with 3 grams of bile salts plus the aloes and podophyllum mixture, the bile collected and analyzed every 24 hours (CX 97, p. 3, Table II; R. 12940, Vol. II, 596-597). Dr. Ivy testified that the addition of the aloes and podophyllum mixture to the diet ". . . had no significant effect. You see the addition of the bile salts caused an increase in bile salt output. When we added to the bile salts the aloes-podophyllum mixture, no further increase occurred" (Id. at 599).

Dr. Ivy explained that the bile salts were added to the diet because "there was a possibility that bile salts might increase the action and absorption of the active ingredients of podophyllum and aloes . . . and then, too, we are simulating normal conditions associated with the normal flow of bile into the intestines." Dr. Ivy explained that bile "normally flows into our intestines, and in the experiment in Table I (CX 97) there was no bile in the intestine, there was no bile salt there. You see, the bile salts are the active ingredients of bile, insofar as digestion is concerned" (R. 12940, Vol. II, 591).

In order to determine what would happen when the same experiment is repeated a number of times on the same animal, Dr. Ivy made 7 tests on 1 dog. During the controlled period the dog was given a meal with no bile salts for 3 days, during which time the bile was collected, measured and analyzed. The dog was next given the same meal except 3 grams of bile salts were added for 3 days and the bile collected, measured and analyzed. Then the dog was given a meal containing 3 grams of bile salts and in addition thereto an aloes and podophyllum mixture equivalent to 3 of petitioner's laxative pills for 3 days and the bile collected, measured and analyzed (CX 97, p. 4, Table III; R. 12940, Vol. II, 595, 596). Dr. Ivy testified that the result of these experiments ". . . shows that the addition of the aloes-podophyllum mixture to the bile salts had no effect on the output of the bile or the choleric acid content of the bile" (Id. at 603).

Dr. Carlson testified that he was familiar with the method employed in the tests made by Dr. Ivy; that he had read them and studied them. When asked if they were accepted and recognized as proper methods to be used in the scientific tests of this nature, he said: "They certainly are" (R. 12940, Vol. I, 384). Dr. Ivy also testified that the methods used by him are accepted and officially recognized in the field of laboratory experiments as being the proper methods to determine the formation and flow of bile (Id. Vol. II at 577).

Dr. Herman Annegers, one of petitioner's witnesses, who assisted Dr. Ivy in the experiments, stated that no dog was used until they were certain that the dog was normal and putting out a constant volume of bile (R. 12940, Vol. II, 910-911). Dr. Annegers further stated that the results of the tests made by Dr. Ivy showed that petitioner's pill had no effect on the formation or flow of bile (Id. at 910, 919-921).

Dr. Ivy stated that the results of his experiments on the animals was transferrable to man; that "there is nothing known which stimulates the flow of bile in a dog

that does not stimulate the flow of bile in a human being. . . .'' He stated that the functional activities of the liver of the dog and of the human being ''vary significantly in one respect, and that is as to the metabolism or [sic] uric acid,'' that ''the human being excretes uric acid in the urine and the dog oxidizes it to allantoin.'' (R. 12940, Vol. II, 622, 624; Vol. IV, 1513). See also the testimony of petitioner's witness, Dr. Crandall, to the same effect (R. 15373, Vol. VII, 2914), and the testimony of Dr. Bollman (R. 12940, Vol. IV, 1478).

Dr. Lloyd W. Hazelton, a witness for petitioner stated that his experiments on dogs and other animals were for the purpose of making the results available to the clinicians (R. 15373, Vol. II, 823).

b. There Is No Relationship Between Constipation and the Secretion or Flow of Bile

Dr. Ivy testified that there is no relationship between constipation and bile flow. He said ''you can divert the bile from the intestines of dogs and human beings without getting constipation'' (R. 12940, Vol. II, 541).

Dr. Bollman stated that he did not think that constipation would bring about a condition which would cause the flow of bile to be so small that the process of digestion and absorption would be affected (R. 12940, Vol. IV, 1414). He stated that ''the concensus of modern, informed medical opinion is that there is no relationship between constipation and the secretion of bile by the liver (R. 12940, Vol. IV, 1497).

He stated that the absence of bile from the intestine would result in the fat being contained in the fecal matter and ''give rise . . . to soft bulky stools and diahrrea'' (R. 12940, Vol. IV, 1415).

Dr. Crandall, petitioner's witness, testified that he did not think constipation under any circumstances decreased the flow of bile to such an extent as to affect the digestive process. He said that he knew of no evidence to this effect (R. 12940, Vol. IV, 1672).

In addition to the above opinions expressed by these expert witnesses that there is no relationship between constipation and the flow of bile, the record contains experiments in relation to this subject conducted by Dr. Ivy and Dr. Bollman.

i. Experiments Conducted by Dr. Ivy to Determine if Constipation Affects the Flow of Bile

Dr. Ivy performed certain experiments on dogs and human beings. Dr. Ivy testified that he was interested "in seeing if we simulated a condition of constipation in the human being," whether petitioner's laxative pill "would promote the formation of bile" (R. 12940, Vol. II, 609-617; Vol. IV, 1518-1536). Dr. Ivy testified that he ran a controlled test period for 2 or 3 days, in which the dogs were fed daily their usual standard diet, their bile collected, measured and analyzed. He then ran a test period for 2 or 3 days in which the dogs were daily fed their standard diet to which had been added bone meal and the bile collected, measured and analyzed. He said that thereafter petitioner's laxative pills were administered to these dogs; one animal 14 pills were given in 2 days; another animal 20 pills were given in 3 days; and the third animal 20 pills were given in 2 days, until "we obtained a cathartic effect from the pills", at which time "we stopped the test," (id. Vol. II, 216). He stated that by this effect he meant "a mushy stool." Dr. Ivy further testified that when catharsis was obtained, the animals were not upset. He testified that the bile was collected, measured and analyzed. He stated that the results of these experiments were that "constipation per se did not change, or did not reflexly decrease the output of bile, and the pills did not significantly increase the output of the bile, and the catharsis did not significantly increase the output of bile, that is, on the average" (R. 12940, Vol. II, 618).

In his experiments on human beings who claimed to be constipated, Dr. Ivy stated that after the subjects had fasted 12 to 15 hours, a duodenal tube was passed into the

stomach and the gastric contents evacuated and then the tube was passed into the duodenum and the duodenal drainage was collected for 1 hour. At the end of the hour a warm sodium chloride solution was introduced through the tube into the duodenum, the drainage tube clamped off for 5 minutes, and then the drainage was collected for the remainder of the second hour. At the end of the second hour, four of petitioner's laxative pills which had been ground and suspended in a warm saline solution, were injected into the duodenum, and the tube washed out with a warm saline solution. The drainage was collected every hour for 4 hours after the injection of the solution of laxative pills.

During the next week these subjects were given 4 of petitioner's laxative pills before retiring and were to continue this dose each night until extensive laxation or cramping occurred, in which event they were to cut the dose to 2 laxative pills. At the end of the week, the second series of these experiments were conducted under identical conditions as those that pertained to the first series (R. 12940, Vol. IV, 1521-1526).

Dr. Ivy testified that "because of the variable nature of our own duodenal drainage" he "would not risk [his scientific reputation] and conclude on the basis of this data" that the taking of petitioner's laxative pill for 1 week "caused sufficient irritation of the colon to bring about reflex contraction of the sphincter" (R. 12940, Vol. IV, 1532). He stated that although the data was "in places statistically significant," he would not state the petitioner's laxative pill "increases the flow of bile into the duodenum." He said that if he concluded "from the data" that it did, then he also had to conclude that the "administration of petitioner's laxative pill for a week caused a spasm of the sphincter of oddi which decreased the flow of bile into the duodenum to a figure less than it was before they took" petitioner's laxative pills (id. at 1533).

This conclusion of Dr. Ivy coincides with the opinion expressed by petitioner's principal witness, Dr. Killian, who stated that on the basis of his experiments he could not make the general statement that petitioner's laxative pills taken for the relief of constipation until the stools averaged 100 grams a day and normal movement is restored, resulted in an increase in the flow of bile into the duodenum (R. 12940, Vol. III, 1234-1236).

ii. Experiments Conducted by Dr. Bollman to Determine if Constipation Affects the Flow of Bile [11]

Before discussing the experiments of Dr. Bollman, we think it necessary to answer some of the unwarranted attacks made by petitioner upon this outstanding scientist.

Dr. Bollman had consistently testified in the original hearings that there is no causal relationship between constipation and the flow of bile. At a hearing on remand petitioner's counsel read an article to the effect that there is a causal relationship between constipation and bile and asked Dr. Bollman if he agreed with it. Dr. Bollman stated that he did. When Dr. Bollman on redirect examination was asked how he reconciled that answer that he agreed with the article to his testimony that there is no causal relationship between constipation and the flow of bile, he replied that he could not reconcile such an answer. He said he had made a mistake in stating that he agreed with the article, and wanted ". . . to change that answer . . ." Dr. Bollman was only stating that he had made a mistake and wanted to correct it. The matter is that simple (R. 15373, Vol. VIII, 3415-3416).

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[11] Petitioner criticizes Dr. Bollman for not using more than 3 dogs. Dr. Bollman stated the reason for this was because ". . . the findings on these 3 dogs were essentially the same and quite conclusive to my mind" (R. 12940, Vol. IV, 1413). He went on to say that he had arrived at the same conclusion years ago in performing similar experiments and that literature contained matters corresponding with his findings and for this reason he saw "no particular point in repeating the same thing" (id. at 1413).

On page 73 of its brief, petitioner again attempts to convince the Court that Dr. Bollman in one of his published articles has stated that there was a causal relationship between constipation and bile flow. Petitioner's counsel read a statement appearing in an article, of which Dr. Bollman was co-author, and he asked Dr. Bollman: "If that statement is correct, it is possible, is it not, that there is a connection between some function of the liver and the physiological processes which cause constipation?" Dr. Bollman replied: "One would have to say that it is possible, yes." (R. 15373, Vol. VIII, 3259). But he went on to say, however, in this same connection, ". . . I know of no direct connection, no cases where a direct connection has been shown." He said: "I cannot recall ever having heard of anything that would substantiate a relation in that regard" (Id. at 3423).

Petitioner tells the Court (Br. 73-79) that certain excerpts from articles by well-known scientists on the causal relationship between constipation and bile flow were read to Dr. Bollman and that he agreed with the statements therein made. Petitioner contends that in agreeing to these statements, Dr. Bollman contradicted his own testimony. There is no foundation for this. In those instances in which Dr. Bollman agreed with a specific statement made in an article, Dr. Bollman explained that while it was true, ailments of the gall bladder and other parts of the gastro-intestinal tract frequently occurred along with constipation, there was no "causal" relationship between such ailments and bile flow (R. 15373, Vol. VIII, 3394, 3415-3417).

Petitioner criticizes Dr. Bollman in reference to his statements made as to the method used in preparing Commission's Exhibit 202, and again claims Dr. Bollman was caught in an untruth.

The evidence (R. 15373, Vol. VIII, 3356-3366), we believe, will establish the following facts: Dr. Bollman prepared Commission's Exhibit 202 to determine the physiological

significance of the data of Dr. Morrison's experiments. He said that in preparing Respondent's Exhibits 349, 350 and 351, to determine the physiological significance of the data applicable to each of these exhibits, he used the same method he used in preparing Commission's Exhibit 202. Respondent's Exhibits 349, 350 and 351 were prepared for publication. Commission's Exhibit 202 was not prepared for publication. Dr. Bollman stated when exhibits are being prepared for publication in medical journals, the publishers prefer statistical treatment of the data. He submitted the data of Respondent's Exhibits 349, 350 and 351 to a statistician for determination of the statistical significance of the data relating to these exhibits. He himself did not make the statistical determination. It appears, therefore, that when Dr. Bollman stated that he had used the same method in preparing Respondent's Exhibits 349, 350 and 351, he was referring to the method employed by him to determine the physiological significance and not the method employed by the statistician. In this respect Dr. Bollman was telling the truth.

It is true that Dr. Bollman testified that at times undue absorption of water was associated with constipation (R. 15373, Vol. VIII, 3240). He stated, however, that this was not always true either in dogs or man in that fecal matter might be retained in the colon for such a period of time as to irritate the colon and thus cause secretion of water, so that the feces contained more water than normal (Id. at 3411).

Dr. Bollman testified that the fecal matter found in the colons of the three dogs, used by him in his experiments, corresponded to what they would have been during constipation (R. 15373, Vol. VIII, 3241). He stated if the fecal matter had been present in the colons of human beings as long as it was in the colons of the dogs, "the composition of the fecal material would be essentially similar" to what it was in the dogs' colons (Id. at 3408).

To summarize Dr. Bollman's position on the subject of

the relationship of constipation and bile flow, he testified that insufficient bile flow would bring about "a fat soap stool which is soft because of the failure of fat digestion . . ." and "diarrhea frequently accompanies" such a stool (R. 15373, Vol. VIII, 3415).

Dr. Bollman performed experiments on 3 dogs for the purpose of ascertaining whether intestinal obstruction affected the secretion of bile by the liver.[12] He sectioned the terminal end of the colon near the beginning of the rectum. Then invaginating in the same manner as is done in an appendectomy, with both ends of the sections being treated in the same way (CXs 199B, 200C, 201B; R. 15373, Vol. VI, 2469). By this surgery complete intestinal obstruction was obtained—so that there was no possibility of any material passing further down the colon (R. 12940, Vol. IV, 1387-1388, 1399; R. 15373, Vol. VI, 2469, 2611).[13]

With the dogs thus completely obstipated, they were fed 150 grams of meat and 100 grams of Karo syrup daily (R. 12940, Vol. IV, 1388).[14] Dr. Bollman testified that the dogs ate the diet daily, which indicated that they were in good condition, that their digestion was going on; that

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[12] See CXs 195A, 195B, 195C, 196, 197A, 197B, 198A-B, 199A-E, and 200G.

[13] In its brief, petitioner indicates that this type of experiment was out of the ordinary. However, Dr. Crandall, one of petitioner's witnesses stated that he had performed the same type experiments on dogs in which he had accomplished "a complete obstruction of the colon" which corresponds to the condition of the dogs that Dr. Bollman operated on. (R. 15373, Vol. VII, 2909).

[14] Petitioner contends (Br. pp. 102-103) that this diet was an exceedingly high carbohydrate diet and protects the liver from injury and that because of this the results of Dr. Bollman's experiments were worthless. Dr. Bollman testified that this was not in his opinion a high carbohydrate meal (R. 15373, Vol. VIII, 3334). He stated that he did not give that diet to protect the livers of the dogs. He said: "Had I been attempting to make the liver more resistant I would have given much less meat and much more carbohydrate." Dr. Bollman stated that he selected this diet because he thought it was best suited for these experiments and explained the reasons (R. 12940, Vol. IV, 1389-1390, 1494-1495).

their liver was functioning adequately. He stated that in experimental conditions where the liver has been damaged or the biliary duct occluded, the dogs will not eat normally (R. 12940, Vol. IV, 1391, 1394, 1400, 1407). Dr. Bollman further stated that an autopsy on these dogs showed that all of the food was completely digested and that all that was left in the colon was the residue (R. 12940, Vol. IV, 1411-1412). He said that the autopsy also disclosed that the colons of these dogs were distended because the feces could not escape. He stated that this distention, however, did not in any way affect the ability of the livers of these dogs to produce bile (R. 12940, Vol. IV, 1413).[15]

Dr. Bollman further testified that the duodena of these animals were not distended (R. 12940, Vol. IV, 1452-1454).

To determine whether the livers of the dogs continued to function properly and without any damage up to the time of their death, Dr. Bollman used two recognized liver function tests: bromsulfoldin test and bilirubin retention test.[16] Dr. Bollman stated that in the bromsulfoldin test 76.5 milligrams of bromsulfoldin in a salt solution was injected intravenously. He stated this injection was made for the purpose of determining whether any bromsulfoldin was retained by the blood. He stated the blood was examined 30 minutes, 45 minutes and 60 minutes after the injection. He said that this is one of the tests to deter-

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[15] Dr. Bollman testified that when he performed the operation on these dogs he concluded that their livers were functioning properly. He said his conclusion was based upon his experience in performing numerous similar operations (R. 12940, Vol. IV, 1393-1394).

[16] In addition to those two tests to determine whether the dogs' livers were functioning, Dr. Bollman performed autopsies on these dogs and testified that from examination of the contents of their colons, their livers were functioning properly during the tests, so as to carry on normal digestion. He stated that there was no residue of fat in the colon above that which was normally to be expected when the liver was secreting sufficient bile. (R. 15373, Vol. VIII, 3433-3442).

mine whether or not the liver will remove bromsulfoldin from the blood at a normal rate—if it does, the liver is functioning normally; if it does not and bromsulfoldin is found in the blood, then the liver is not functioning normally (R. 15373, Vol. VI, 2463-2466).

Dr. Bollman stated that the bilirubin retention test was for the purpose of determining whether bilirubin was present in the blood of these dogs; that the normal blood of a dog contains no bilirubin, and if bilirubin is present, it indicates that bilirubin has not been secreted by the liver but reabsorbed by the blood. He said that this is the liver functioning test to determine whether or not the liver is excreting bile pigments properly. He stated that the dog plasma is perfectly clear; that if the dog plasma has a yellow color it indicates that bilirubin is present and that the dog's liver is slightly but very definitely impaired; that if the plasma is water clear it indicates that the liver was functioning normally and that there was no impairment thereof (R. 15373, Vol. VI, 2466-2467).

Dr. Bollman stated that if the operations performed on these dogs had so injured their livers as to prevent the flow of bile, there would have been bile pigment and bromsulfoldin in the blood (R. 15373, Vol. VIII, 3428-3429).

Dr. Bollman stated that the result of these liver functioning tests upon these dogs established the fact that the livers were functioning properly since there was no bromsulfoldin or bile pigment in their blood (R. 12940, Vol. IV, 1392-1395, 1396-1397, 1406).

At the conclusion of his experiments on the dogs, Dr. Bollman performed autopsies on these dogs. He stated that from these autopsies the colon of the dog had no fat content "as high as one would expect if fat had not been absorbed." (R. 15373, Vol. VIII, 3440-3442). This indicates that there was sufficient bile present in the gastrointestinal tract to provide for the absorption of fat. When asked if there was sufficient bile in the intestines of the three dogs to carry on the functions of bile in the digestive

system, Dr. Bollman replied: "Yes, I am sure that there was sufficient bile in the gastro-intestinal tract to carry out all of the digestion functions of bile in these dogs during the entire course of the experiments" (R. 15373, Vol. VIII, 3422).[17]

Dr. Bollman testified that the failure of bile to flow into the duodenum would cause the human being to have larger stools and softer stools and more frequent stools (R. 15373, Vol. VIII, 3407-3408). Obviously, this is different from constipation. Dr. Bollman's conclusion that there was no relationship between constipation and bile flow corresponds with the testimony of petitioner's witness, Dr. Crandall, who testified that he did not think "constipation under any circumstances decreased the flow of bile to such an extent that there is not sufficient bile in the duodenum to carry on the function of bile in the human digestive process." He stated that he knew of no evidence indicating that constipation would so decrease the secretion of bile (R. 12940, Vol. IV, 1672).

c. Petitioner's Laxative Pills Will Have No Effect Upon the Gall Bladder

The Commission found (R. 15373, Vol. I, 303) that petitioner's laxative pill will not cause the gall bladder to contract or cause relaxation of the sphincter of Oddi or prevent its contraction in the first instance or serve in any way to milk bile from the ampula of Vater or the bile duct, and concluded that petitioner's laxative pill will not increase the flow of bile or any constituent thereof into the duodenum. This finding of the Commission is supported by the uncontradicted opinion of qualified experts.

Dr. Carlson testified that petitioner's laxative pill will not cause the laxation of the sphincter of Oddi muscles,

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[17] In its brief (pp. 99-100) petitioner contends that Dr. Bollman's testimony as to the autopsies he performed was improperly received because he did not produce supporting data. A short reply to this, if any is needed, is that at the time of Dr. Bollman's testimony, petitioner made no objection to the receipt of his testimony.

that irritants such as aloes and podophyllum would cause the reverse. He stated that to his knowledge, or the knowledge of literature, there was no substance in petitioner's laxative pill which would cause the gall bladder to contract and force bile into the intestine. He stated that this was the consensus of competent, informed medical opinion (R. 12940, Vol. I, 373-374).

Dr. Carlson further testified that "the evidence is to the effect that these drugs have no effect on the emptying of the gall bladder." He stated that he knew of no conflict of competent, informed medical opinion as to this action of aloes and podophyllum upon the gall bladder. He said "that there is no action on the gall bladder, or the mechanism of the gall bladder by these two drugs, singly or combined." He stated that this is the consensus of competent, informed medical opinion (R. 12940, Vol. I, 358, Vol. II, 502-503).

Dr. Ivy testified that in his opinion aloes and podophyllum in petitioner's laxative pill will not aid in the evacuation of the gall bladder and that this represented the consensus of modern, informed, competent medical opinion (R. 15373, Vol. II, 490-494; R. 12940, Vol. II, 726). Dr. Carlson testified that the drugs aloes and podophyllum were at one time considered cholagogues but "not any more." He stated that this was the opinion some 50 or 60 years ago "but with a better understanding of the machinery of the liver and the machinery of the evacuation of the bile, that is changed" (R. 12940, Vol. II, 489-490).

Dr. Ivy testified that he was familiar with modern text books on Pharmacology and they classified aloes and podophyllum as "irritant cathartics." He stated that podophyllum is not considered to be a cholagogue at the present time and that aloes has never been referred to "as a cholagogue in any of the text books of pharmacology or materia medica" (R. 12940, Vol. II, 556-557).

Dr. Carlson and Dr. Ivy testified that there is no substance in petitioner's laxative pill which would cause the

formation of cholesystokinin, the hormone which causes the gall bladder to contract (R. 12940, Vol. I, 369-370; Vol. II, 553, 721).

In addition to this uncontradicted opinion of these experts, the record contains experiments performed by scientists which demonstrate that petitioner's laxative pill will have no effect upon the contracting or emptying of the gall bladder.

i. Experiments Conducted by Dr. Ivy to Determine if Petitioner's Laxative Pill Will Have Any Effect Upon the Gall Bladder

Dr. Ivy conducted a series of three experiments upon a group of large dogs for the purpose of determining whether aloes and podophyllum (1) would cause the liver to secrete or form bile, and (2) would cause the gall bladder to contract.

Dr. Ivy anesthetized the dogs and inserted a canula into the dome of their gall bladders so that the contraction of the gall bladder could be graphically recorded. He "put a canula in the common bile duct" so that the bile coming from the liver could be collected and graphically recorded. The gall bladders of these dogs were not taken out (CX 98, p. 1; RX 13; R. 12940, Vol. II, 627-630). Dr. Ivy was asked if the fact that the dogs were anesthetized would make any difference, to which he replied: "No." (R. 15373, Vol. II, 717).

With the dogs thus prepared, Dr. Ivy injected into the dogs the hormone cholesystokinin, which causes the gall bladder to contract and the hormone secretin, which causes the liver to secrete bile (R. 12940, Vol. II, 629). When Dr. Ivy was asked why he used these known stimuli on the gall bladder and the liver, he replied: "We wanted to be sure that the animal was responsive, had a responsive liver and gall bladder before proceeding with the experiment" (R. 15373, Vol. II, 717). Dr. Ivey went on to say that to determine the effect of an unknown substance, such as petitioner's laxative pill, on the gall bladder or on the liver is to compare the effect of the unknown sub-

stance with the effect of the known substance, chloesytokinin and secretin (R. 12940, Vol. II, 717), and that this was an improved method of carrying out such a test (R. 15373, Vol. II, 717).

After the effects of the injections of cholesystokinin and secretin had worn off (R. 12940, Vol. II, 630) six of petitioner's laxative pills were ground and dissolved in alcohol, diluted with water and injected intravenously twelve times in seven dogs. Dr. Ivy stated that the alcohol was used because podophyllum is a resin and will not dissolve appreciably in water. He stated that the same amount of alcohol was used as was used during the control period; that the alcohol when injected slowly, as it was done, had no effect during the control period (R. 12940, Vol. II, 634-635).

When Dr. Ivy was asked whether or not the injection of six of petitioner's laxative pills as above described, had any effect upon the flow of bile or contraction of the gall bladder, he replied: "No." (Id. at 634).

A half an hour after the above test was made, the same solution consisting of four of petitioner's laxative pills was introduced into the duodenum of the dogs by means of a syringe and needle (R. 12940, Vol. II, 634-635). The gall bladder was observed for half an hour; then the duodenal injections were repeated. Dr. Ivy testified that the duodenal injections had no effect on the gall bladder. In four of the experiments on seven dogs, a solution equivalent to two of petitioner's laxative pills was injected intravenously and repeated in about 10 minutes. The dogs were observed for 3 hours or more (CX 98, p. 2; R. 12940, Vol. II, 627-643).

When Dr. Ivy was asked what were the results of this first series of seven experiments, he replied that there was nothing in petitioner's laxative pill "which, when administered intravenously in alcohol solution or which when introduced into the duodenum caused the contraction of the gall bladder or resulted in the flow of bile or the formation of bile by the liver" (R. 12940, Vol. II, 636).

After the effect of the above experiments on the dogs had worn off, a second series of experiments were performed. Twelve experiments were performed in which four of petitioner's laxative pills were ground, dissolved in water at body temperature and slowly injected into the duodenum. Dr. Ivy stated that water was used for these experiments instead of alcohol for the purpose of trying petitioner's laxative pill "in various media." He said that later on we digested them in two different ways (R. 12940, Vol. II, 641-643). After one and one-half to two hours, 2 of petitioner's laxative pills were dissolved in a solution of alcohol and water and injected slowly intravenously into the dogs.

After the completion of the above series of experiments a third series was performed using the same control period and the same injections of cholesystokinin and secretin as were carried out as in the other experiments. Four of petitioner's laxative pills were ground in 2 cc. of pancreatic juice and 0.05 cc. bile, "incubated for 1 to 6 hours in a water bath maintained at 37°C." after which the solution was injected into the duodenum (R. 12940, Vol. II, 643-647).[18]

When Dr. Ivy was asked the results of this series of experiments, he said that petitioner's laxative pills "administered intravenously or intraduodenally in appropriate solution do not influence the formation of bile or the pressure on the gall bladder, or cause the gall bladder to contract" (CX 98, p. 23; R. 12940, Vol. II, 642).

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[18] Petitioner criticizes (Br. pp. 21-25) the "mixtures" which Dr. Ivy injected into the dogs. There is no merit to this criticism. Dr. Ivy, who was recognized by petitioner's witness Dr. Crandall as "one of the outstanding experimental physiologists in the world," (R. 15373, Vol. VII, 2896), testified that the mixture used is the same as is found in the duodena of dogs and human beings; it would facilitate digestion of the pills, that is, "the way a scientist approaches the problem" (R. 12940, Vol. II, 644, 645-648). Petitioner offered no evidence that the "mixture" was not proper.

ii. Experiments Conducted by Dr. Case to Determine if Petitioner's Laxative Pill Will Have Any Effect Upon the Gall Bladder [19]

Dr. Case performed a series of experiments on 7 human beings, including himself, for the purpose of determining whether petitioner's laxative pill had any effect upon the gall bladder. He used the Graham-Cole method of visualizing the gall bladder by means of the X-ray. Dr. Case stated that although this method is primarily used for diagnostic purposes "it is the best method there is" for testing the efficacy of drugs on the function of the liver and gall bladder and on the integrity of the gall bladder (R. 12940, Vol. I, 404-405; R. 15373, Vol. VII, 3093-3094, Vol. VIII, 3149).

Dr. Case had the subjects, on the afternoon of the day before the X-ray examination, take a gall bladder dye which made it possible to visualize the bile concentrated in the gall bladder. The subjects had a carbohydrate meal, so that there would be no effect of the meal upon the gall bladder. Bile accumulates and becomes concentrated in the gall bladder when the subject is fasting or has had only a carbohydrate meal (R. 12940, Vol. I, 1404-1406).

Before breakfast the next day the first X-ray picture was taken of the subjects' gall bladders (CXs 99, 102, 106, 108, 112, 115 and 118).[20] Immediately after the X-ray picture was taken, the subjects were given 3 of petitioner's laxative pills—in one case 6 of these pills. 2, 4 or 5 hours there-

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[19] Petitioner attempts to convince the Court (Br. 44-49) that Dr. Case was so biased and prejudiced that his testimony was unworthy of belief. This same contention was made before the Commission. The Commission rejected it and in doing so held that "Dr. Case's status as an eminent radiologist and his high qualifications to conduct and evaluate scientific research work was apparent from the record. . . . the views expressed by [Dr. Case] constituted sincere scientific interpretations and opinions reached by him on the basis of his years of medical experience and training." (R. 15373, Vol. I, 297).

[20] CX 99, R. 12940, Vol. I, 411-412, 414; CX 102, Id. 423-424; CX 105, Id. 428-429; CX 108, Id. 432-433; CX 112, Id. 438, 441-442; CX 115, Id. 439, 446; CX 118, Id. 450-451.

after, with the subject still fasting, a second X-ray picture was taken (CXs 100, 103, 106, 109, 113, 116, 119, 120).[21] The second X-ray picture was made to determine "what influence the administration of these pills had upon the gall bladder" (R. 12940, Vol. I, 408). After the second X-ray picture was taken the subjects ate a fat meal and from 30 minutes to an hour thereafter, the third X-ray picture was taken (CXs 101, 104, 107, 110, 114, 117, 121).[22]

Dr. Case testified that a fat meal "calls for bile for assistance in digestion and when the fat gets into the stomach and starts passing on down to the small bowel, there is a reflex process which calls upon the gall bladder . . . [the] sphincter opens up and the gall bladder contracts and bile passes on into the intestine." He said the X-ray disclosed a change in the size of the gall bladder (R. 12940, Vol. I, 409).

The results of Dr. Case's tests showed that petitioner's laxative pill had no effect on the gall bladder, whereas the pictures taken 30 minutes after a fat meal showed that the gall bladders of all the subjects were greatly reduced in size.[23]

When Dr. Case was asked as to the effect of petitioner's laxative pill on the gall bladder, the evacuation of the gall bladder, and the flow of bile from the gall bladder as shown by his X-ray experiments, he replied: "It has no effect." He also added that the tests showed that petitioner's laxative pills had no effect upon the formation of bile by the liver (R. 12940, Vol. I, 457-458).

Petitioner complains that the Commission made no report upon its challenges of the experiments and testimony

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[21] CX 100, R. 12940, Vol. I, 417-419; CX 103, Id. 425-426; CX 106, Id. 429; CX 109, Id. 433-434; CX 113, Id. 441-442; CX 116, Id. 439, 446-447; CX 119, Id. 452-453; CX 120, Id. 453.

[22] CX 101, R. 12940, Vol. I, 419-420; CX 104, Id. 427; CX 107, Id. 429; CX 110; Id. 433-434; CX 114, Id. 442; CX 117, Id. 448-449; CX 121, Id. 453.

[23] R. 12940, Vol. I, 421-456.

of Dr. Case. There is no merit to this statement and the findings of the Commission flatly contradict petitioner in that respect. See R. 15373, Vol. I, 297-298.

Having no evidence in the record upon which it can rely to offset the impact of the experiments and testimony of Dr. Case, petitioner attempts to discredit the testimony of this witness (Br. 51-65). Petitioner contends (1) that Dr. Case "was permitted to testify, without producing the underlying records of the tests, as to the results of X-ray films made" during those tests; (2) that Dr. Case did not produce X-ray films of the tests made on subjects upon which experiments were performed. This contention is out of time.

Dr. Case identified Commission's Exhibits 99 through 110, 112 through 121 as prints of the original X-ray films and testified in reference to these. These prints were offered in evidence and petitioner's counsel stated that he would not "consent to these pictures going into evidence. . . . I want to be in a position to raise whatever objections I want to later on, without having the embarrassment of having consented to their going in." All of the prints were received into evidence (R. 12940, Vol. I, 412, 418-420, 440-441). Upon the completion of the cross-examination of Dr. Case, counsel in support of the complaint stated that references had been made concerning the original films and he would like to introduce into evidence the original films from which Commission's Exhibits 99 through 121, except Exhibit 111, had been made. Petitioner's counsel said: "No objection." (R. 15373. Vol. II, 610). The examiner upon that statement admitted the original films into evidence as Commission's Exhibits 125 through 146. It is too well settled as to require either citation of authority or argument that in order to take advantage of any error that might result in the admission either of testimony or exhibits, objections must be made at the time such testimony or exhibits are offered in evidence. In the instant matter petitioner's counsel stated there was no objection.

He is now estopped from raising any question as to the validity or credibility of either the testimony of Dr. Case or the authenticity of the films. In *Noonan* v. *Caledonia Gold Mining Co.*, 121 U.S. 393, 400 (1887) the Supreme Court said:

> "The rule is universal, that where an objection is so general as not to indicate the specific grounds upon which it is made, it is unavailing on appeal, unless it be of such a character that it could not have been obviated at the trial. The authorities on this point are all one way. Objections to the admission of evidence must be of such a specific character as to indicate distinctly the grounds upon which the party relies, so as to give the other side full opportunity to obviate them at the time, if under any circumstances that can be done."

Had petitioner made a specific objection to the introduction of these exhibits or to the testimony of Dr. Case at the time the exhibits and his testimony were introduced into the record, the underlying records could and would have been made available to petitioner (R. 15373. Vol. VIII, 3135-3136). Had petitioner complained that Dr. Case had not produced all of the X-ray films at the time Dr. Case testified, these additional X-ray films could and would have been made available to petitioner. Petitioner's objections here come some ten years too late.

We note some of petitioner's criticisms of the experiments conducted by Dr. Case. Petitioner criticizes the Commission for permitting Dr. Case to testify in reference to X-ray films which he himself did not take (Br. p. 57). There is no merit to this. The series of X-ray films on three of the subjects were made in Dr. Case's office, and either he took them or they were taken in his presence; he testified in the minutest details as to the procedure followed (R. 15373, Vol. II, 529-530). The X-ray films for the other four subjects were made at Northwestern University in the Department of which Dr. Case was the head (id. 514);

all were made by either of two technicians (id. 534-535) whose names appear on the X-ray films themselves (id. Vol. VII, 3050-3051). In its opinion (id. Vol. I, 320-321) the Commission pointed out that Dr. Case was well qualified to testify regarding the X-ray films.

Petitioner also criticizes the interpretation made by Dr. Case of the X-ray films as well as the protocol of the experiments, stating that sufficient time had not elapsed between the giving of the pills before Dr. Case took the second series of X-ray pictures to establish that it was not the pills but the fat meal which caused the gall bladders of the subjects to appear shrunken in the third series of pictures (Br. pp. 59-66). There is no merit to this. Dr. Case stated specifically that from the thousands of gall bladder tests he had made by the method employed in these experiments it was a "reasonable and entirely logical *conclusion that it was the fat meal that did the contracting and not*" petitioner's laxative pills. (R. 15373, Vol. VII, 3105-3106). Dr. Case further testified that if a drug has any cholagogic effects, the gall bladder will begin the process of emptying when the drug is taken by mouth from six to ten minutes after the cholagogic is taken (Id. Vol. VIII, 3149, 3150).

d. Petitioner's Laxative Pill Will Not Affect the Flow of Bile in Any Manner

The Commission found, and it is not contradicted in the record, that the various ways in which an increase in the flow of bile into the duodenum can be brought about are: (1) to stimulate the formation or secretion of bile by the liver; (2) to cause the gall bladder to contract; (3) to cause the sphincter of Oddi to relax; (4) to irritate the intestine in such manner as to eliminate the reflex action which causes contraction of the sphincter of Oddi; and (5) to milk the bile from the bile ducts or from the ampulla of Vater by increasing the motility of the duodenum. (R. 15373, Vol. I, 277).

Dr. Carlson testified that the sphincter of Oddi is a circular muscle surrounding the common bile duct in the wall of the duodenum. When it contracts it compresses the

lumen of the bile duct so that bile cannot escape (R. 12940, Vol. I, 459-461).

Dr. Ivy testified that the ampulla of Vater "is a little dilation or enlargement in the portion of the common bile duct just before the common bile duct opens into the [lumen] of the intestine." (R. 12940, Vol. II, 528-529).

Dr. Ivy also testified that on the basis of his knowledge "[Petitioner's laxative] Pills or aloes and podophyllum do not relax the sphincter of Oddi." (R. 12940, Vol. II, 720-721). He said there is no proof that [Petitioner's laxative] Pills caused "sufficient irritation of the colon to bring about reflex contraction of the sphincter." (R. 12940, Vol. IV, 1519, 1532).

Having determined by various experiments hereinabove set out that neither petitioner's laxative pill nor the two drugs of which it is composed would have any effect on the formation of bile by the liver and on the gall bladder's contraction, and to complete his studies on the subject of the therapeutic effect of petitioner's laxative pill, Dr. Ivy performed 10 experiments on 6 jejunal fistula dogs to find out "whether or not the passage of [petitioner's laxative pills], or their ingredients, through the duodenum might act to relax the sphincter of Oddi, or to increase the motility of the duodenum . . . or affect the sphincter in such a way that the flow of bile into the duodenum might be increased" (R. 12940, Vol. IV, 1499).

Each dog was anesthesized and the jejunum was cut approximately 24 inches below the outlet of the stomach. The distal portion of the section was closed and the proximal portion was brought to the outside through a stab wound.

"A snugly fitting funnel was placed around the fistula for purposes of collection of the secretions." The secretions passed into the duodenum down to the jejunum and out through the jejunal fistula. (R. 12940, Vol. IV, 1500) After the dogs had fully recovered from the anesthetic, the tests were begun. The first 4 hours constituted the

control period. The next 4 hours constituted the test period. During the control period each dog was given 100 ccs. distilled water by stomach tube every hour for 4 hours. At the end of each hour the secretions were collected, measured and tested for bilirubin and for cholic acid.

The test period started at the beginning of the fifth hour, at which time each dog was given by means of a stomach tube, 100 ccs. of distilled water in which 4 of petitioner's laxative pills were suspended. This was repeated at the beginning of each hour. At the end of each hour the secretions were collected, measured and tested by scientific methods for bilirubin and for cholic acid (R. 12940, Vol. IV, 1500-1501). Dr. Ivy stated: "The bilirubin determination in the hourly drainage was determined in all tests, and the cholic acid was determined in tests only in 3 dogs" (Id. at 1503).

Dr. Ivy testified that the results of these tests indicated that there was an increase in volume of secretion collected during the test period as compared with the volume collected during the control period. He stated that while this increase was mathematically significant " . . . it is not physiologically significant . . . Because there was no increase in the bile pigment in the drainage, nor in the cholic acid in the drainage, after the administration of [petitioner's laxative pills]" (R. 12940, Vol. IV, 1508-1509). Dr. Ivy further said ". . . the average figures on bilirubin output and cholic acid output per hour simply indicates or shows clearly that the increase in the volume was not due to an increase in the flow of bile in the duodenum." (id. at 1510). Dr. Ivy stated that the tests made on these dogs could be translated to man, "because he knows of nothing which increases the flow of bile into the duodenum of dogs which does not do so in the case of man, and vice versa" (Id. at 1513).

From his experiments Dr. Ivy concluded that petitioner's laxative pill did not increase the flow of bile into the duodenum by "milking" bile out of the common bile duct (R.

12940, Vol. IV, 1512-1513) or the ampulla of Vater (Id. 1628-29).

The above is a summary of the evidence upon which the Commission relied to make its finding that petitioner's laxative pill will not affect the flow of bile.

In its effort to establish that its laxative pill will affect the flow of bile, petitioner introduced the experiments and testimony of Drs. Killian, Hazelton and Morrison.

Dr. Killian, who petitioner says was its "key witness" (Br. p. 112), testified that petitioner's laxative pill will increase the flow of bile if three conditions are present at the same time. Petitioner does not quote Dr. Killian, but summarizes in its own language the three conditions and then tells the Court (Br. p. 107): "Now, of course, these were the very conditions in which petitioner's product was intended, designed and claimed to benefit." It is extremely difficult to believe that petitioner is serious in this statement. It indicates, however, the desperate straits in which petitioner finds itself in its attempt to offset the overwhelming weight of the evidence in the record upon which the Commission based its finding that petitioner's laxative pill will have no effect on the formation or flow of bile.

In substance, Dr. Killian testified that the results of his experiments indicated that petitioner's laxative pill will increase the flow of bile when taken under three conditions —all three of which must be present and complied with at the same time.

First Condition. Petitioner's laxative pill must be taken in sufficient doses over a sufficient period of time to "produce laxation either within normal limits of fresh weight stools or the maximum laxative effect" (R. 12940, Vol. III, 1305). Dr. Killian stated that to accomplish this, 5 of petitioner's laxative pills must be taken every day for 1 week. He admitted that what is a normal limit of fresh weight stools varies in the individual and from time to time (id. at 1292, 1329). Dr. Killian stated that he was

not willing to say that if a person met this requirement that it would mean the flow of bile would be increased (Id. at 1236).

Second Condition. "The rate of flow of bile into the duodenum will be increased in individuals and, only in individuals who show during periods within which they have been taking no [petitioner's laxative] pill 'low values' for the biliary constituents in the duodenal fluid in response to a stimulus introduced into the duodenum of the type of Peptone" (R. 12940, Vol. III, 1305). It is obvious that the only way this condition can be met is by having a duodenal drainage performed. This can only be done in a laboratory or a hospital. Dr. Killian admitted that unless the purchaser of the pills had had duodenal drainage performed, he would not know whether such drainage was high or low and unless he did know, he would not be in a position to tell whether petitioner's laxative pill would have any effect upon the flow of bile (id. at 1250). Again Dr. Killian was not willing to say that even though this second condition was met together with his other conditions, petitioner's laxative pill would secure an increase in bile flow (Id. at Vol. IV, 1361).

Third Condition. Petitioner's laxative pill will increase the flow of bile "in individuals who show signs during periods in which they are not taking [petitioner's laxative pill] of diminished rates of intestinal motility as indicated by abnormally low fresh weight stools and symptoms depending upon the abnormally low rate of intestinal motility" (R. 12940, Vol. III, 1305-1306). This condition of Dr. Killian is difficult of interpretation. Petitioner interprets it to mean "that the individual be one who shows signs when not taking the pills of low or diminished rates of intestinal mobility [sic], as indicated by abnormally small stools or absence of stools" (Br. p. 107). Just as in the other two conditions, this condition is impossible of practical fulfillment. There is no definite standard applicable to all persons as to what is a diminished rate of intes-

tinal motility. Different periods of time, as Dr. Ivy testified, are required for different persons for the fecal matter to pass through into the intestines (id. Vol. IV, at 1557). Dr. Ivy also testified there are no specific signs or symptoms of "diminished rates of intestine motility" (Id. at 1557-1559).

The end result of the experiments and testimony of Dr. Killian is that petitioner's laxative pills would increase the flow of bile *only when taken under the three above-described conditions*. It is difficult, if not impossible, for a purchaser of petitioner's laxative pill to meet those requirements. There is nothing in the record which establishes the fact that petitioner in its directions for use advises a purchaser that before he can obtain the relief he seeks he must comply with all of the three conditions testified to by petitioner's chief witness, Dr. Killian. Further than this, Dr. Killian would not state that petitioner's laxative pill would increase the flow of bile when either one, two or all of those conditions were actually met. (R. 12940, Vol. III, 1326).

Petitioner introduced the experiments and the testimony of Dr. Lloyd W. Hazelton in support of its contention that this laxative pill will increase the flow of bile. The method and procedure followed by Dr. Hazelton established the fact that neither his experiments nor his testimony are material or relevant to the issue here.

Dr. Hazelton injected aloes and podophyllum intravenously into the dogs. He testified that from his experiments he could not tell whether or not aloes and podophyllum taken duodenally had any effect upon the flow of bile (R. 15373, Vol. II, 794). Dr. Hazelton testified that from his experiments he could not and did not determine whether petitioner's laxative pills taken orally would have any effect upon the flow of bile (id. at 795) and, reiterated, that his experiments offered no proof at all that petitioner's laxative pills taken orally would have any effect whatever (id. at 816). Since in his experiments Dr. Hazelton injected

aloes and podophyllum intravenously into the dogs and in the experiments conducted by the Commission's witnesses these drugs or petitioner's laxative pills were injected into the duodenum of the dogs, the experiments are totally different. There is no conflict between the results obtained. Dr. Hazelton's experiments are not relevant.

An examination of the testimony of Dr. Morrison will convince the Court that it cannot properly be characterized as reliable evidence. Dr. Morrison received a fee of between $17,500 and $20,000 from petitioner for experimental work. (R. 12940, Vol. III, 1092, 1093). Patients had been referred to Dr. Morrison by other physicians for treatment. Without the knowledge of these patients or consent, he subjected them to the duodenal drainage and the administration of petitioner's laxative pills for the furtherance of the project for which he had been employed and paid by petitioner. He also charged these patients for services. Dr. Morrison did not inform the physicians of these patients that he was using the patients for the purpose of his experiments (R. 12940, Vol. III, 1101-1102, 1113, 1117, 1129, 1133-1134).

After testifying for 4 days in which he submitted the entire case histories of the 53 patients upon which he performed his various experiments (R. 12940, Vol. III, 1109-1112), Dr. Morrison objected to further testifying and employed a personal counsel to make this objection (R. 15373, Vol. III, 1313-1317). When a motion to strike Dr. Morrison's testimony was made, petitioner's counsel objected and filed an affidavit in support of his objection (Id. Vol. I, 11-14).

Dr. Morrison testified (R. 12940, Vol. III, 1108) that he made his laboratory findings in 1941 and wrote them up on stationery which bore his postal zone number in Philadelphia.[24] It was stipulated on the record that postal zones

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[24] PX 136E, R. 12940, Vol. III, 1108; PX 137E, id. at 1108; PX 138E and F, R. 15373, Vol. III, 1139; PX 140E, id. at 1155; PX 146C, id. at 1199-1200; PX 147B, id. at 1202-1203; PX 160F, id. at 1276. PX refers to Respondent exhibits.

were not adopted by the Post Office Department in Philadelphia until May 1943 (R. 15373, Vol. III, 1135)—2 years subsequent to the time Dr. Morrison testified he wrote up the laboratory findings. For other testimony of Dr. Morrison establishing his unreliability, see R. 12940, Volume III, 1117, 1130-1131; R. 15373, Volume III, 1204-1206, 1275.

Those are the three witnesses whose testimony petitioner relies upon to establish the fact that its laxative pill will increase the flow of bile.

The above summary of the only evidence introduced in the record by petitioner on the issue of flow of bile establishes: (1) The conditions which Dr. Killian stated would have to be present in order for petitioner's laxative pill to increase the flow of bile are wholly unrealistic and impossible; (2) The tests performed by Dr. Hazelton are not relevant because the aloes and podophyllum were introduced intravenously into the dogs. Petitioner's laxative pills are not sold to be used by the purchaser in that manner and there is nothing in the record to indicate that they ever have been so used; and (3) The record discloses that the testimony of Dr. Morrison cannot properly be characterized as substantial evidence.

We, therefore, submit that the findings of the Commission that petitioner's laxative pills will have no effect on the formation or flow of bile is not only based upon substantial evidence but upon the only reliable evidence in the record relevant thereto.

2. Petitioner Was Not Denied a Fair and Impartial Hearing

Under Point II (Br. pp. 114-145) petitioner contends that it was denied a fair and impartial hearing. As we read petitioner's brief, the basis for its contention is: the examiner (1) made rulings adverse to petitioner; (2) used objectionable language; (3) adopted the contention of counsel supporting the complaint; (4) denied petitioner's offer of proofs; and (5) refused to admit certain evidence.

Petitioner states (Br. p. 122) that the decision of this Court in *Carter Products, Inc.* v. *Federal Trade Commis-*

sion, 201 F.2d 446 (C.A. 9, 1953), held that petitioner had been denied a fair trial, for reasons other than the curtailment of the cross examination of Drs. Case, Bollman and Lockwood. The opinion of the Court will not support this statement. At page 454, the Court said: "It is argued that there was ample evidence from other quarters to sustain the findings and order of the Commission, hence the rulings, even if wrong, were not prejudicial. We are of the opinion, however, that the cumulative effect of these unjustifiable restrictions on the cross-examination of key witness for the Commission was to deprive petitioner of a fair hearing."

In its order reopening this matter after receiving the remand from this Court, the Commission remanded the case to hearing examiner James A. Purcell (R. 15373, Vol. I, 31). Petitioner raised no objections to this at the time nor was any objection made at any time during the course of the hearings. It was not until the examiner closed the record that petitioner filed its motion before the Commission seeking disqualification of the examiner (id. 145-147). The contention that the examiner was biased and prejudiced relates, therefore, to the hearings on remand.

The Court should bear in mind that this case was heard by the Commission under a procedure in which the examiner files only a recommended decision as provided by the rule of the Commission in effect when the proceedings were instituted.[25] The examiner in the instant matter did not make an initial decision as under the present procedure. Here the Commission made its own findings as to the facts, its own conclusions and issued its own order to cease and desist. The alleged bias and prejudice of the examiner,

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[25] "The trial examiner shall within 15 days after receipt by him of the complete stenographic transcript of all the testimony in a proceeding, make his report upon the evidence. . . . the trial examiner's report is not a report or finding of the Commission. Such report is advisory only and is not binding upon the Commission" (16 C.F.R. Sec. 2.20, Cum. Supp., June 2, 1938, June 1, 1943; 6 F.R. 832 (February 4, 1941).

therefore, even if true, is immaterial. In *National Labor Relations Board* v. *Air Associates, Inc.*, 121 F.2d 586, 588 (C.A. 2, 1941), the Court said:

> " . . . Even if bias against respondent was manifested in the examiner's intermediate report and recommendations, that bias became immaterial, since the Board ignored that report and relied solely and directly on the evidence in the record. . . . That the Board disregarded the examiner's report serves to answer respondent's objections concerning bias, if any, disclosed in his report. . . ."

In *National Labor Relations Board* v. *Ford Motor Company*, 114 F.2d 905 (C.A. 6, 1940), cert. denied 312 U.S. 689, the Court said:

> " . . . Not all departures from strict propriety . . . justify a reviewing court in setting aside decision in a hearing upon which so much time and effort has been spent as upon this. Material prejudice to the interest of the complaining litigant must clearly appear. It may be conceded that the trial examiner in the present case overstepped the bounds of that judicial propriety which contestants have a right to expect not only from courts but from administrative tribunals, and is so conducive to public confidence in their adjudications, and that he manifested a peculiar concept of the nature of the judicial function he was called upon to exercise. Indeed, the Board does not condone his lapses. *We must keep in mind, however, that ultimate decision was not his but that of the Board. . . .*" (Id. at 909) (Emphasis supplied.)

We submit, therefore, that any bias and prejudice of the examiner which may have existed cannot form a basis for a determination that petitioner was denied a fair and impartial hearing unless the examiner committed some act either in refusing to admit testimony, exhibits or in restricting the rights of petitioner in some manner resulting in prejudicial error. Adverse decisions, statements and

comments made by examiner do not form the basis of a charge of personal bias and prejudice, *Berger* v. *United States,* 255 U.S. 22, 31.

In the Air Associates, Inc. case (121 F.2d 586, 590 (C.A. 2, 1941) the Court held that "over jealous scrutiny of every word that may fall from the judge's mouth" is not compatible with the Court's duty in insuring impartial conduct of the trial.

The fact that the Commission's findings of fact were in accord with the position advocated by counsel in support of complaint and against the position advocated by petitioner's counsel, cannot form the basis of a charge of personal bias or prejudice. If it could, this is, in effect, saying that whenever a decision goes against an advocate it establishes bias or prejudice of the Court or agency making the decision. This statement carries its own absurdity. In *Williapoint Oysters* v. *Ewing,* 174 F.2d 676 (C.A. 9, 1949), cert. denied 338 U.S. 860, this Court said at page 689:

> Merely because the findings were in accord with the contentions and evidence of the Government does not demonstrate to us that the Administrator considered only Government evidence and disregarded that of petitioner.

Petitioner further contends that the fact that the examiner refused to admit into evidence articles and excerpts from so-called "textual authorities" established his bias and prejudice. There is no merit to this. As a matter of fact, although the examiner did refuse to admit the articles in evidence, as such, he did permit petitioner's counsel to read excerpts from 14 different "textual authorities," asking Dr. Bollman in each instance whether or not he agreed with them (R. 15373, Vol. VIII, 3183-3200, 3202, 3206). The admission into evidence of these "textual authorities" could not have accomplished any greater purpose than was accomplished by reading excerpts therefrom. Petitioner had full advantage of these articles to test Dr.

Bollman as to whether or not he agreed or disagreed with the statements.

Insofar as the offer of these articles was for the purpose of establishing the truth of their contentions, this Court stated in *Carter Products, Inc.* v. *Federal Trade Commission,* 201 F.2d 446, 449 (C.A. 9, 1953):

> "The general view is that medical treatises are not in themselves competent evidence since they constitute statements made out of Court by persons not available for cross examination."

If they were offered in evidence for the purpose of impeaching Dr. Bollman, the admission of them was within the discretion of examiner and his refusal did not amount to an abuse of discretion. (Id. at 248-249).

Petitioner further contends that in refusing to admit into evidence the testimony of a statistician and the testimony and experiments of Dr. Twiss, the examiner disclosed personal bias and prejudice. This is without merit.

The purpose of the additional hearings was to correct the errors laid bare by this Court's review. After this was accomplished, petitioner offered the testimony of a statistician and the testimony and experiments of one Dr. Twiss. Counsel for the Commission (R. 15373, Vol. I, 237-238) said he would offer no objection if this was newly discovered evidence. Then when the proceeding came before the Commission, it took some pains during oral argument to ascertain whether petitioner had something concrete to offer in the way of evidence. One of the Commissioners during argument asked petitioner's counsel the following: ". . . I was wondering if you could make a statement to the Commission which would perhaps satisfy the requirements of that rule [in reference to the admission of this proposed evidence], and perhaps demonstrate by a statement its materiality and the reasons why it wasn't produced at the original hearing." To which petitioner's counsel replied: ". . . It wasn't available. It

hadn't been done at the time of the original hearing. . . . I have asked the Commission in my appeal to do two things: Either dismiss the complaint in its entirety because of the conflict of scientific proof, or if that not be done, then to start it all over again before another trial examiner. . . . I don't care to take advantage of the suggestion made by [counsel supporting the complaint] and on what my position will be with respect to that evidence, I would like to reserve decision." The Commission then asked if counsel stated that this proposed evidence is material and presently available. To which petitioner's counsel replied: "Yes, the evidence is presently available and is very material" (R. 15373, Vol. VIII, 3495-3497). The Commission in its opinion, speaking through Commissioner Kern (R. 15373, Vol. I, 326), said: ". . . The Commission having determined that [petitioner's] motion to disqualify the hearing examiner was not well taken, we must reject the [petitioner's] contention that it is entitled to a trial de novo. [Petitioner] having elected not to pursue the matter further by filing for our consideration a proper motion and having an evident intent to rely on the rulings below as constituting prejudicial error invalidating all prior proceedings herein, it was appropriate that the Commission proceed to a consideration of the case on its merits. This the Commission has done and its decision, representing the results of its own extensive examination of the record, is issuing herewith."

We submit that petitioner's failure to properly proceed to introduce into this record what it claimed to be after discovered evidence which would definitely establish that its laxative pill would increase the flow of bile, is a strong indication that the evidence would not establish this fact. Petitioner cannot stand aside during the course of a proceeding and then parry an adverse decision with an offer of more evidence, *Colorado Radio Corp.* v. *Federal Communications Commission,* 118 F.2d 24, 26 (C.A.D.C., 1941), nor can a petitioner put aside its claim of newly discovered

evidence as this petitioner did before the Commission and then parry an adverse decision with the claim of prejudice. To the same effect see: *California Lumbermen's Council* v. *Federal Trade Commission,* 115 F.2d 178, 183 (C.A. 9, 1940); *Dolcin Corporation* v. *Federal Trade Commission,* 219 F.2d 742, 747 (C.A.D.C., 1954).

IV

CONCLUSION

We respectfully submit that the Commission's findings that petitioner's laxative pill will have no effect on the formation or flow of bile is not only supported by the greater weight of the evidence but by the only substantial evidence in the record relating thereto; that all other findings of fact not here in issue and the prohibitions in the order based thereon are final and conclusive.

The Commission, therefore, prays that the petition to review be dismissed and that pursuant to the statute[26] the Court enter its decree affirming the Commission's order to cease and desist and remanding petitioner to obey the same and comply therewith.

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WASHINGTON, D. C., NOVEMBER 20, 1957.

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[26] "To the extent that the order of the Commission is affirmed, the Court shall thereupon issue its own order commanding obedience to the terms of such order of the Commission." Federal Trade Commission Act, § 5(c), 52 Stat. 113; 15 U.S.C. § 45(c).

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